IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TEXARKANA DIVISION

UNITED STATES OF AMERICA, *et al.*, *ex rel.* [UNDER SEAL], **Plaintiff,** **v.** **[UNDER SEAL],** **Defendants.**	**Civil Action No.** 5:18CV-61 RWS **COMPLAINT AND JURY DEMAND** **Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)**

FILED UNDER SEAL

NOT TO BE FILED ON PACER

HEALTH SELECTION ALLIANCE, LLC, on behalf of the UNITED STATES OF AMERICA; STATE OF ARKANSAS; STATE OF CALIFORNIA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; DISTRICT OF COLUMBIA; STATE OF FLORIDA; STATE OF GEORGIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF MARYLAND; COMMONWEALTH OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MINNESOTA; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE OF OKLAHOMA; STATE OF RHODE ISLAND; STATE OF TENNESSEE; STATE OF TEXAS; STATE OF VERMONT; COMMONWEALTH OF VIRGINIA; and STATE OF WASHINGTON,

Plaintiffs/Relator;

v.

EMD SERONO, INC.; BRIGHTSTAR FRANCHISING LLC; MAXIM HEALTHCARE SERVICES, INC.; INTEGRITY NURSING, LLC; UNITED BIOSOURCE PATIENT SOLUTIONS, INC. f/k/a PROHERANT HEALTH, INC.; and MCKESSON CORPORATION,

Defendants.

Civil Action No. 5:18cv-61 RWS

COMPLAINT AND JURY DEMAND

Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

The United States of America (the "United States") and the Plaintiff States (defined below) (the United States and Plaintiff States are collectively referred to herein as the "Government"), by and through their *qui tam* Relator Health Selection Alliance, LLC, and its affiliates (the "Relator"), allege:

PRELIMINARY STATEMENT

1. This is a civil action brought on behalf of the Government under 31 U.S.C. § 3730(e)(4) of the United States False Claims Act, 31 U.S.C. § 3729 *et seq.* ("FCA" or "False Claims Act"), the Federal Anti- Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(B) ("AKS" or "Anti-Kickback Statute"), the United States Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. ("FDCA"), and the false claims acts of the respective Plaintiff States[1] to recover treble

[1] The state statues are: the: (1) Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. §§ 20-77-901 – 911 (as amended by 2017 Arkansas Laws Act 978 (S.B. 564)); (2) California False Claims Act, Cal. Gov't Code §§ 12650 – 12656; (3) Colorado Medicaid False Claims Act, Colo. Rev. Stat. Ann. §§ 25.5-4-303.5 – 4-310; (4) Connecticut False Claims and Other Prohibited Acts Under State-Administered Health or Human Services Programs Act, Conn. Gen. Stat. Ann. §§ 4-274 – 289; (5) Delaware False Claims and Reporting Act, Del. C. Ann. tit. 6, §§ 1201 – 1211; (6) District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012, D.C. Code Ann. §§ 2-381.01 – 381.10; (7) Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 – 68.092; (8) Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 – 4-168.6; (9) Hawaii False Claims to the State Act, Haw. Rev. Stat. Ann. §§ 661-21 – 31; (10) Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. §§ 175/1 – 175/8; (11) Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. §§ 5-11-5.5-1 – 5.5-18; (12) Iowa False Claims Act, Iowa Code Ann. §§ 685.1 – 685.7; (13) Louisiana Medical Assistance Programs Integrity Law, La. Stat. Ann. §§ 437.1 – 440.16; (14) Maryland False Claims Act, Md. Code Ann. Health-Gen. §§ 8-101 – 111; (15) Massachusetts False Claims Law, Mass. Gen. Laws Ann. ch. 12, §§ 5A – 5O; (16) Michigan Medicaid False Claim Act, Mich. Comp. Laws Ann. §§ 400.601 – 400.615; (17) Minnesota False Claims Act, Minn. Stat. Ann. §§ 15C.01 – 15C.16; (18) Montana False Claims Act, Mont. Code. Ann. §§ 17-8-401 – 416; (19) Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010 – 357.250; (20) New Hampshire Medicaid Fraud and False Claims Act, N.H. Rev. Stat. Ann. §§ 167:61-b – 61-e; (21) New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 – 32C-18; (22) New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 – 14-15; (23) New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 – 9-14; (24) New York False Claims Act, N.Y. Fin. Law §§ 187 – 194; (25) North Carolina False Claims Act, N.C. Gen. Stat. Ann. §§ 1-605 – 618; (26) Oklahoma Medicaid False Claims Act, Okl. Stat. Ann. tit. 63, §§ 5053 – 5054; (27) Rhode Island State False Claims Act, R.I. Gen. Laws Ann. §§ 9-1.1-1 –1.1- 9; (28)

damages sustained by and civil penalties and restitution owed to the Government as a result of a multi-tiered kickback scheme involving defendants EMD Serono, Inc., a subsidiary of Merck KGaA, Brightstar Franchising LLC, Maxim Healthcare Services, Inc., Integrity Nursing, LLC, United BioSource Patient Solutions, Inc. f/k/a Proherant Health, Inc., and McKesson Corporation, referred to herein as "Defendants".

2. Defendants' unlawful conduct involves EMD Serono, Inc.'s products (1) Serostim, and (2) Saizen. Collectively, Serostim and Saizen are referred to herein as the "Covered Drugs."

3. To enrich themselves at the expense of the Government, EMD Serono, Inc. ("Serono"), with substantial assistance from Brightstar Franchising LLC ("Brightstar), Maxim Healthcare Services, Inc., ("Maxim"), Integrity Nursing, LLC ("Integrity"), United BioSource Patient Solutions, Inc. f/k/a Proherant Health, Inc. ("Proherant"), and McKesson Corporation ("McKesson"), referred to herein as "Defendants", resorted to three intertwined, unlawful marketing schemes for the Covered Drugs.

4. First, Serono contracted with and paid remuneration to Brightstar, Maxim, Integrity, Proherant, and McKesson to deploy Nurse Educators to recommend Serostim and Saizen to Prescribers[2] and patients, and also to supply *quid pro quo* Nurse Educator and Support Services to providers. While purporting to provide independent medical advice and disease-awareness information, the nurses were in reality acting as undercover sales reps for Serono,

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Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 – 108; (29) Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 – 185; (30) Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132; (31) Vermont False Claims Act, Vt. Stat. Ann. tit. 32, §§ 630 – 642; (32) Virginia Fraud Against Tax Payers Act, Va. Code Ann. §§ 8.01-216.1 – 216.19; and (33) Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. §§ 74.66.005 – 74.66.130.

[2] As used herein, the term "Prescriber" refers to any physician or Advance Practice Provider authorized to write prescriptions, as well as their employers.

focused on the singular mission Serono had paid them to accomplish: drive prescribers and patients to Serostim and Saizen.

5. Second, with assistance from McKesson, Brightstar, Maxim, Integrity, and Proherant, Serono provided in-kind remuneration to prescribers in the form of reimbursement support services, saving providers thousands of dollars in administrative expenses. These reimbursement support services were provided to induce providers to prescribe the Covered Drugs to their patients.

6. Third, with assistance from McKesson, Brightstar, Maxim, Integrity, and Proherant, Serono provided in-kind remuneration to prescribers in the form of free nursing services to induce them to prescribe Serostim and Saizen to their patients.

7. The federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS"), expressly prohibits any individual or entity from offering, paying, soliciting, or receiving any "remuneration," which includes "any kickback, bribe, or rebate," to "any person to induce such person" to purchase or recommend a drug or service that is covered by Medicare or Medicaid. *Id.* Further, the U.S. Department of Health and Human Services (the "HHS") has repeatedly warned pharmaceutical companies that they should refrain from engaging in marketing or promotional activities that rely on individuals involved in the delivery of healthcare or on the provision of free services such as billing, nursing, or other staff services. *See, e.g.*, 56 Fed. Reg. 39952; 59 Fed. Reg. 65372.

8. Although Serono and its co-defendants knew that the AKS prohibited them from providing anything of value to providers or from giving kickbacks to promote the Covered Drugs, Defendants disregarded the law, choosing instead to put sales growth and profits before their duties to comply with federal law and ensure patient safety and integrity in the healthcare

marketplace. The AKS ensures that the Government pays only for conflict-free medical care and prescriptions that are provided in the best interests of the patient. A kickback eliminates any sound basis for such assurance because it taints the prescribing physician's medical decisions with the prescriber's financial interests. "The Government does not get what it bargained for when a defendant is paid by [the Government] for services tainted by a kickback." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011) (internal quotations omitted).

9. As is demonstrated below, Defendants' conduct caused tens of thousands of prescriptions for the Covered Drugs that were not based purely on clinical efficacy or patient-specific information, but rather were tainted by the unlawful, substantial kickbacks Serono offered prescribers.

10. Based on Defendants' illegal marketing and promotion schemes, pharmacies have and continue to submit claims to Medicare and Medicaid that were tainted by kickbacks, causing these programs to pay billions of dollars in improper reimbursements.

JURISDICTION AND VENUE

11. This Court has jurisdiction over the Government's claims pursuant to 28 U.S.C. §§ 1331 and 1345.

12. This Court may exercise personal jurisdiction over EMD Serono, Inc. ("Serono"), with substantial assistance from Brightstar Franchising LLC ("Brightstar), Maxim Healthcare Services, Inc., ("Maxim"), Integrity Nursing, LLC ("Integrity"), United BioSource Patient Solutions, Inc. f/k/a Proherant Health, Inc. ("Proherant"), and McKesson Corporation ("McKesson"), because a substantial part of the acts giving rise to the Government's claims occurred within the State of Texas.

13. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1391(c) because Serono, Brightstar, Maxim, Integrity, Proherant, and McKesson each transact business in this District and/or, in furtherance of its fraudulent kickback schemes, caused to be submitted or conspired to submit false claims in this District.

THE PARTIES

14. EMD Serono, Inc. ("Serono") is a subsidiary of Merck KGaA, a multinational drug company headquartered in Germany. Serono markets and sells pharmaceuticals throughout the United States, and is headquartered in Rockland, MA.

15. Brightstar Franchising LLC ("Brightstar"), is a home care and medical staffing agency whose corporate headquarters is in Gurnee, IL.

16. Maxim Healthcare Services, Inc. ("Maxim"), is a home care and medical staffing agency whose corporate headquarters is in Columbia, MD.

17. Integrity Nursing, LLC ("Integrity"), is a medical staffing company, but it specializes in nurse staffing for both military health fairs and per-diem positions for "Patient Education For Self Injectable Drugs," according to its website.

18. United BioSource Patient Solutions, Inc. f/k/a Proherant Health, Inc. ("Proherant"). Proherant is known as United BioSource Patient Solutions, Inc., following the purchase by Express Scripts Holding Company ("Express"). Express is headquartered in St. Louis, MO, and their 2015 revenues were $101 billion.

19. McKesson Corporation ("McKesson"). McKesson's corporate headquarters are in San Francisco, CA. In the fiscal year that ended on March 31, 2016, McKesson had net revenues of $190 billion.

20. Relator Health Selection Alliance, LLC ("HSA"), and its affiliates, is a New Jersey based healthcare fraud research organization. Each year, HAS representatives conduct

hundreds of interviews of participants in the healthcare marketplace – nurses, sales reps, office managers, administrators, reimbursement support personnel, and allied medical professionals – to form an understanding of industry practices.

21. Relator brings this action on behalf of the Government pursuant to the qui tam provisions of the federal False Claims Act, 31 U.S.C. § 3729 *et seq.*, and the false claims acts of the respective Plaintiff States.

STATUTORY BACKGROUND

22. In relevant part, the FCA, 31 U.S.C. § 3729(a)(1)(A)-(C), establishes treble damages liability to the United States for any individual or entity that:

> knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
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> knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or
>
> conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

Within the meaning of the FCA, "knowing" is defined to include reckless disregard and deliberate indifference. *Id.* In addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim.

23. In relevant part, the AKS, 42 U.S.C. § 1320a-7b *et seq.*, provides as follows:

> (b) Illegal Remunerations.
>
> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
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> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

24. For purposes of the AKS, "remuneration" includes the transfer of anything of value, whether cash or in-kind consideration, directly or indirectly, covertly or overtly. Importantly, the statute has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for referral of services or to induce further referrals.

25. The AKS is designed to, among other things, ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry, such that healthcare professionals remain free of conflicts of interest that could impact treatment decisions.

26. To ensure compliance, every federally-funded health care program requires every provider or supplier to ensure compliance with the provisions of the AKS and other federal laws governing the provision of health care services in the United States.

27. The AKS was amended in March 2010 as part of the Patient Protection and Affordable Care Act ("PPACA"), which clarified that "[a]n AKS violation that results in a federal health care payment is a per se false claim under the FCA." *United States ex rel. Lutz v. Bluewave Healthcare Consultants, Inc.*, 853 F.3d 131, 136 (4th Cir. 2017); 42 U.S.C. § 1320a-7(b)(g). The PPACA also amended the Social Security Act's "intent requirement" to make clear that violations of its anti-kickback provisions, like violations of the FCA, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." Pub. L. No. 111-148, 124 STAT. 759 § 6402 (adding new section, § 1128J(h)).

28. The courts have recognized that claims for reimbursement for medical care tainted by illegal kickbacks are "false" claims within the meaning of the FCA. *See, e.g., United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 315 (3d Cir. 2011); *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 392-93 (1st Cir. 2011).

29. Knowingly providing kickbacks to providers to induce them to prescribe a drug (or to influence provider prescriptions) for individuals who seek reimbursement for the drug from a federal Government healthcare program or causing others to do so, while certifying compliance with the AKS (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates the FCA.

30. A violation of the AKS constitutes a felony. Any party convicted under the AKS must be excluded from federal health care programs for a term of at least five years. 42 U.S.C. § 1320a.

31. Compliance with the AKS is required for reimbursement of claims from federal health care programs, and claims made in violation of the law are actionable civilly under the FCA. 42 U.S.C. § 1320a-7b(g) (2010) (stating, in part, that a "claim that includes items or services resulting from a violation of ... [the AKS] constitutes a false or fraudulent claim for

purposes of [the FCA] ... . "); *see also US. ex ref. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 315 (3d Cir. 2011) (stating "[c]ompliance with the AKS is clearly a condition of payment under Parts C and D of Medicare"). Compliance with the AKS is thus a fundamental and material aspect of what the government purchases when it pays for medical care for federally insured beneficiaries.

32. The AKS contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. See 42 U.S.C. § 1320a-7b(b)(3). None of the statutory exceptions or regulatory safe harbors protects Defendants from liability for the conduct alleged herein.

33. The Plaintiff states each has enacted statutes that are parallel to the legislative scheme embodied in the FCA and the AKS.

AFFECTED HEALTH PROGRAMS

34. For the drugs at issue in this case, generally, when a physician prescribes a drug, a patient is provided with a prescription that is then filled at a pharmacy. The pharmacy then submits the claim for payment to the relevant federal health care program(s) for reimbursement.

35. In certain circumstances, a federal program may also have pharmacy facilities that directly dispense prescription drugs. In such cases, the federal health care program purchases the drug directly rather than reimbursing the pharmacy.

Medicare

36. Medicare is a federal program that provides federally-subsidized health insurance primarily for persons who are 65 or older or disabled. *See* 42 U.S.C. §§ 1395 *et seq.* ("Medicare Program").

37. Part D of the Medicare Program was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, to provide

prescription drug benefits for Medicare beneficiaries. Medicare Part D became effective January 1, 2006.

38. All persons enrolled in Medicare Part A and\or Medicare Part B are eligible to enroll in a prescription drug plan under Part D. HHS, through its component agency, the Center for Medicare and Medicaid Services ("CMS"), contracts with private companies (or "Part D sponsors") to administer prescription drug plans. Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D sponsors enter into subcontracts with many pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

39. Generally, after a physician writes a prescription for a patient who is a Medicare beneficiary, that patient can take the prescription to a pharmacy to be filled. When the pharmacy dispenses drugs to the Medicare beneficiary, the pharmacy submits a claim electronically to the beneficiary's Part D sponsor (sometimes through the sponsor's pharmacy benefit manager, or "PBM"). The pharmacy receives reimbursement from the sponsor (or PBM) for the portion of the drug cost not paid by the beneficiary. The Part D sponsor is then required to submit to CMS an electronic notification of the drug dispensing event, called the Prescription Drug Event ("PDE"), which contains data regarding the prescription claim, including the service provider of the drug, the prescriber of the drug, the quantity dispensed, the amount it has paid to the pharmacy, and whether the drug is covered under the Medicare Part D benefit.

40. Payments to a Part D Plan sponsor are conditioned on the provision of information to CMS that is necessary for CMS to administer the Part D program and make payments to the Part D Plan sponsor for qualified drug coverage. 42 C.F.R. § 423.322. CMS's instructions for the submission of Part D prescription PDE claims data state that "information ...

necessary to carry out this subpart" includes the data elements of a PDE. PDE records are an integral part of the process that enables CMS to administer the Part D benefit. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program.

41. CMS gives each Part D sponsor advance monthly payments consisting of the Part D sponsor plan's direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage, and estimated low income subsidies. 42 C.F.R. §§ 423.315, 423.329. At the end of the payment year, CMS reconciles the advance payments paid to each Part D sponsor with the actual costs the sponsor has incurred. In this reconciliation process, CMS uses the PDE claims data it has received from the Part D sponsor during the prior payment year to calculate the costs the Part D sponsor has actually incurred for prescriptions filled by Medicare beneficiaries under Part D. If CMS underpaid the sponsor for low-income subsidies or reinsurance costs, it will make up the difference. If CMS overpaid the sponsor for low-income subsidies or reinsurance costs, it will recoup the overpayment from the sponsor. After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. 42 C.F.R. § 423.336.

42. CMS's payments to the Part D sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R.§ 423.315(a).

43. In order to receive Part D funds from CMS, Part D Plan sponsors, as well as their authorized agents, employees, and contractors (including pharmacies), are required to comply with all applicable federal laws, regulations, and CMS instructions.

44. By statute, all contracts between a Part D Plan sponsor and HHS must include a provision whereby the Plan sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112.

45. Medicare Part D Plan sponsors must also- certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including the FCA and AKS. 42 C.F.R.§ 423.505(h)(l).

46. In accordance with these express statutory and regulatory requirements, all contracts entered into between CMS and Plan D Plan sponsors from 2006 through the present include a provision in which the sponsor "agrees to comply with ... federal laws and regulations designed to prevent ... fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§ 3729 *et seq.*), and the Anti-Kickback Statute (§ 1127B(b)) of the Act."

47. CMS regulations further require that all subcontracts between Part D Plan sponsors and downstream entities (such as pharmacies and PBMs) contain language obligating the entities in question to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

48. A Part D Plan sponsor also is required to certify to the accuracy, completeness and truthfulness of the PDE claims data submitted to CMS. Specifically, the relevant regulatory provision, entitled "Certification of data that determine payment," provides in relevant part:

> (1) General rule. As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part), the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.
>
> (2) Certification of enrollment and payment information. The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.
>
> (3) Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under§ 423.87l(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.

42 C.F.R. § 423.505(k).

49. Compliance with the regulatory requirement that the PDE data submitted to CMS is "true, accurate, and complete" is a condition of payment under the Medicare Part D program.

50. In accordance with this regulatory requirement, since the Part D program began, Medicare required each Part D Plan sponsor to sign annually an Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor ("Attestation"). This Attestation states:

> Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and the Medicare Part D Organization(s) listed above, hereafter referred to as the Part D Organization, governing the operation of the contract numbers listed above, the Part D Organization hereby makes the following attestations concerning CMS payments to the Part D Organization:

> The Part D Organization attests that based on its best knowledge, information, and belief, the final Prescription Drug Event (PDE) data that have been submitted to and accepted by CMS as of [date] with respect to the Part D plans offered under the above-stated contract(s) for the dates of service of January 1, [prior year] to December 31, [prior year], are accurate, complete, and truthful and reflect all retroactive adjustments of which the Part D organization has been informed by May 30, [current year]. In addition, the Part D Organization attests that based on best knowledge, information, and belief, the payments that have been made by the Part D organization for the claims summarized by the aforementioned PDE data were made in accordance with the coordination of benefits guidance in Chapter 14 of the Medicare Prescription Drug Benefit Manual and other applicable CMS guidance. The Part D Organization attests that based on its best knowledge, information, and belief as of the date(s) of last successful DIR [Direct and Indirect Remuneration Data] [prior year] data submission(s) via the Health Plan Management System (HPMS) as listed above, the final direct and indirect remuneration data submitted to CMS for the Part D plans offered under the above-stated contract(s) for the [prior] coverage year are accurate, complete, and truthful and fully conform to the requirements in the Medicare Part D program regulations and the Final Medicare Part D DIR Reporting Requirements for [the prior year]. The Part D Organization also certifies that based on its best knowledge, information, and belief as of the date indicated below, all other required information provided to CMS to support the determination of allowable reinsurance and risk corridor costs for the Part D plans offered under the above-stated contract(s) is accurate, complete, and truthful. With regards to the information described in the above paragraphs, the Part D Organization attests that it has required all entities, contractors, or subcontractors, which have generated or submitted said information (PDE and DIR data) on the Part D Organization's behalf, to certify that this information is accurate, complete, and truthful based on its best knowledge, information, and belief. In addition, the Part D Organization attests that it will maintain records and documentation supporting said information. The Part D Organization acknowledges that the information described in the above paragraphs will be used for the purposes of obtaining federal reimbursement and that misrepresentations or omissions in information provided to CMS may result in Federal civil action and/or criminal prosecution.

51. All approved Part D Plan sponsors who received payment under Medicare Part D in benefit years 2006 through the present date submitted these required Attestations in the same or similar format.

52. Medicare regulations further provide: "If the claims data are generated by a

related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3).

53. Medicare also enters into agreements with physicians to establish the physician's eligibility to participate in the Medicare program. For the physician to be eligible for participation in the Medicare program, physicians must certify that they agree to comply with the Anti-Kickback Statute, among other federal health care laws. Specifically, on the Medicare enrollment form, CMS Form 855I, the "Certification Statement" that the medical provider signs states: "You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below." Those requirements include:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me ... The Medicare laws, regulations and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

54. Lastly, when submitting a claim using the CMS claim form, the provider certifies that the claim, whether submitted by the provider or on the provider's behalf, "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment

including but not limited to the Federal anti-kickback statute . . . ."[3]

Medicaid

55. Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. Each state administers a State Medicaid program.

56. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A). While drug coverage is an optional benefit, the Medicaid programs of all states provide reimbursement for prescription drugs.

57. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Federal funding under Medicaid is provided only when there is a corresponding state expenditure for a covered Medicaid service to a Medicaid recipient. The federal government pays to the state the statutorily established share of the "total amount expended ... as medical assistance under the State plan." 42U.S.C. § 1396b(a)(l).

58. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies generate funding requests to the state Medicaid programs.

59. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each state will be

[3] Centers for Medicare & Medicaid Services, CMS 1500 – Health Insurance Claim Form, *available at* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf (last accessed, April 16, 2018).

permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). 42 C.F.R. § 430.30.

60. Claims arising from illegal kickbacks are not authorized to be paid under state regulatory regimes. In fact, providers who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements, including the AKS. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.

61. Furthermore, in many states, Medicaid providers, including both physicians and pharmacies, must affirmatively certify compliance with applicable federal and state laws and regulations.

62. For example, in New York, physicians and pharmacies must periodically sign a "Certification Statement for Provider Billing Medicaid," in which the provider certifies that claims submitted "to the State's Medicaid fiscal agent, for services or supplies furnished, [...] will be subject to the following certification .... I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations."

63. Similarly, in Texas, some "providers (and submitters on behalf of providers) must affirm that they have read, understood, and agree to the certification and terms and conditions of

the prior authorization request" before submitting each prior authorization request. By agreeing, the provider and authorization request submitter certify that the information supplied concerning the prior authorization "constitute true, correct, and complete information." Further, the provider and authorization request submitter "understand that payment of claims related to this prior authorization will be from federal and state funds, and that falsifying entries, concealment of a material fact, or pertinent omissions may constitute fraud and may be prosecuted under applicable federal and/or state law." The consequences of omitting information or failing to provide true and accurate information are "termination of the provider's Medicaid enrollment and/or personal exclusion from Texas Medicaid."[4]

64. Additionally, "Texas Medicaid service providers are required to certify compliance with or agree to various provisions of state and federal laws and regulations."[5]

TRICARE

65. TRICARE is part of the United States military's health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel, and military retirees and their\dependents. The military health system, which is administered by the Department of Defense ("DOD"), is composed of the direct care system, consisting of military hospitals and military clinics, and the benefit program, known as TRICARE. TRICARE is a triple-option benefit program designed to give beneficiaries a choice

[4] Texas Medicaid Provider Procedures Manual § § 5.5.1.2.1 – 5.5.1.2.3 (Dec. 2017), *available at* http://www.tmhp.com/Pages/Medicaid/Medicaid_Publications_Provider_manual.aspx (last accessed, Dec. 20, 2017).

[5] Texas Medicaid Provider Procedures Manual § 1.6.8 (Dec. 2017) (emphasis in original), *available at* http://www.tmhp.com/Pages/Medicaid/Medicaid_Publications_Provider_manual.aspx (last accessed, Dec. 20, 2017).

between health maintenance organizations, preferred provider organizations, and fee-for-service benefits.

66. TRICARE prescription drug benefits are provided through three different programs: military treatment facility outpatient pharmacies, TRICARE network retail pharmacies, and TRICARE's mail order service. TRICARE contracts with a PBM to administer its retail and mail order pharmacy programs. In-addition, TRICARE beneficiaries can also pay out-of-pocket to fill prescriptions at non-network retail pharmacies, and submit a claim for reimbursement directly with TRICARE's PBM. The claims process is different for each of these pharmaceutical programs.

67. When a TRICARE beneficiary brings a prescription to a TRICARE network retail pharmacy, for example, the pharmacy submits an electronic claim to the PBM for that prescription event. The PBM sends an electronic response to the pharmacy that confirms the beneficiary's TRICARE coverage, and, if the prescription claim is granted, informs the pharmacy of the calculated pharmacy reimbursement amount and the co-pay (if applicable) to be collected from the beneficiary. The pharmacy then collects the co-pay amount (if any) from the beneficiary and dispenses the medication. After a 10-day hold to ensure the prescription was picked up and not returned to the shelf by the pharmacy, the PBM sends a TRICARE Encounter Data ("TED") record electronically to TRICARE. The TED record includes information regarding the prescription event, including the reimbursement amount to be paid to the dispensing pharmacy. TRICARE then authorizes the PBM to make payment to the pharmacy for the amount remaining (after co-pay) on the claim. The PBM sends the payment to the pharmacy. After the payment is made by the PBM's bank, the PBM's bank requests reimbursement from the Federal Reserve Bank ("FRB"). The FRB then transfers funds to the PBM's bank account.

68. If the prescription is filled at a non-network retail pharmacy, the beneficiary must pay the full price of the prescription to the pharmacist and file a claim for reimbursement on DD Form 2642, TRICARE/DOD.CHAMPUS Medical Claim- Patient's Request for Medical Payment ("Form 2642"). The Form 2642 is mailed to the PBM. As in the case of reimbursements under the retail pharmacy program, a TED record is created and sent to TRICARE. TRICARE then authorizes payment to the TRICARE beneficiary. Upon receiving that authorization, the PBM issues a check to the beneficiary, which is drawn on the PBM' s bank account. TRICARE then reimburses the PBM in the same manner as it does under the retail pharmacy program, such that funds are transferred from the FRB to the PBM's bank account.

69. TRICARE beneficiaries can also fill prescriptions through TRICARE's mail order pharmacy program. TRICARE beneficiaries submit prescriptions by mail, fax, or electronically to TRICARE's PBM, along with any co-pay (if applicable). TRICARE's PBM delivers the prescription to the beneficiary via free standard shipping. The medications dispensed through the mail order pharmacy program are filled from the PBM's existing inventory of pharmaceuticals. The PBM then requests replenishment pharmaceuticals from DOD's national prime vendor contracted by Defense Logistics Agency ("DLA"). DOD procures the pharmaceuticals through its national prime vendor and replenishes the PBM's inventory of pharmaceuticals after accumulated dispensing reach full package size amounts. The PBM then submits a TED record to TRICARE to obtain administrative fees in connection with that prescription event. DLA bills TRICARE directly for drug replenishment costs.

70. Pursuant to 38 U.S. C. § 8126, pharmaceutical manufacturers are required to enter into national contracts with the DOD pursuant to which the manufacturer makes available for

procurement certain covered drugs at the Federal Ceiling Price (a price that is calculated as at least 24% less than the manufacturer's average price based on all sales to commercial customers through a wholesaler or distributor). Pursuant to DOD's contract with its national prime vendor, the national prime vendor submits an invoice to the DOD for payment of pharmaceuticals supplied to the PBM in connection with the mail order pharmacy program, charging the DOD the price set by the contract awarded by the DOD to the drug manufacturer.

71. Since March 2003, TRICARE has contracted with a pharmacy benefits manager, Express Scripts, Inc. ("ESI"), to administer TRICARE's mail order pharmacy programs. ESI has also administered TRICARE's retail pharmacy program since June 2004.

72. Similarly, TRICARE's military treatment facilities purchase medications through procurement contracts with third party pharmaceutical prime vendors. When a TRICARE beneficiary submits an outpatient prescription to a military treatment facility's outpatient pharmacy, the pharmacy purchases the medication from the prime vendor pursuant to an existing procurement contract, and the drug is then dispensed to the patient.

73. While some physicians enroll in the TRICARE program as network or participating providers, any physician that is licensed, accredited and meets other standards of the medical community is authorized to provide services to TRICARE beneficiaries. Physicians who are enrolled in the TRICARE network must expressly certify their compliance with TRICARE's regulations. Yet all providers that provide services to TRICARE beneficiaries, whether network providers or non-participating providers, are required to comply with TRICARE's program requirements, including its anti-abuse provisions. 32 C.F.R.§ 199.9(a)(4). TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied. *Id.* § 199.9(b). Kickback arrangements are included within the

definition of abusive situations that constitute program fraud. *Id.* §§ 199.2(b), 199.9(c)(12).

Veterans Administration Health Care

74. The Department of Veteran Affairs ("VA") maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are procured directly by the VA. A VA beneficiary can take a prescription to a VA medical facility, at which point the VA dispenses the medication to the VA beneficiary from its existing inventory. The VA also supports a mail service prescription program as part of its outpatient drug benefit. VA beneficiaries can submit prescriptions to that mail service program, and the VA then dispenses pharmaceuticals purchased by the VA directly to VA beneficiaries. The VA medical system serves approximately four million veterans.

75. The VA purchases the pharmaceuticals that it dispenses at its medical facilities and through its mail service prescription program through its Federal Supply Schedule ("FSS") program. Pursuant to 38 U.S.C. § 8126, pharmaceutical manufacturers are required to enter into national contracts with the VA pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price (a price that is calculated as 26% less than the manufacturer's average price based on all sales to commercial customers through a wholesaler or distributor). AVA facility that requires a supply of a particular medication (including a mail order facility) submits a purchase order to the VA's pharmaceutical prime vendor ("PPV") for distribution of pharmaceuticals.

76. Pursuant to the PPACA, among other things, all claims to Government reimbursed programs resulting from a violation of the AKS are also a violation of the FCA.

77. Moreover, the statutes and regulations set forth above concerning Medicare, Medicaid, TRICARE, and Veterans Administration Health Care, when viewed together, state that healthcare providers must comply with the AKS in order for claims they cause to be

submitted to these programs to be reimbursed.

78. Here, the claims submitted for the Covered Drugs violated the AKS because they stemmed from prescriptions that were tainted by kickbacks, while the participants in the scheme knew that claims for reimbursement would be submitted to the above programs. As such, and as more fully discussed below, the prescribing healthcare providers expressly and impliedly falsely certified compliance with the conditions of payment for, at least, Medicare, Medicaid, TRICARE, and Veterans Administration Health Care.

79. In addition to falsely certifying compliance with the AKS, the healthcare providers also falsely certified compliance with contractual provisions that were conditions for payment.

RELATOR'S INVESTIGATION

80. To unmask Defendants' unlawful conduct, Relator and its representatives interviewed numerous individuals with knowledge of the scheme.

- Confidential Interviewee #1 ("CI-1") a/k/a T.T., is employed by Brightstar as a part time Nurse Educator for Serostim, and she has held the position since January of 2016. Her territory includes the west coast of Florida.

- Confidential Interviewee #2 ("CI-2") a/k/a D.R. was employed by Maxim as a per diem Nurse Educator for Serostim from 2014 until 2015. His territory included Irving, TX and the surrounding area.

- Confidential Interviewee #3 ("CI-3") a/k/a L.T., is employed by Integrity as a per diem Nurse Educator for Serostim and she has held the position since 2013. Her territory includes the States of North Carolina and Virginia.

- Confidential Interviewee #4 ("CI-4") a/k/a K.K. was employed by Brightstar as a

part time Nurse Educator for Serostim from 2013 until 2015. Her territory included Sarasota, FL and the surrounding area.

- Confidential Interviewee #5 ("CI-5") a/k/a H.B. was employed by Proherant as a per diem Nurse Educator for Serostim and Saizen from 2009 until 2014. Her territory included Dallas, TX and the surrounding area.

- Confidential Interviewee #6 ("CI-6") a/k/a T.M. was employed by Serono as a drug rep ("Drug Rep") for Serostim from 2007 until 2014. His territory was the southeast United States.

- Confidential Interviewee #7 ("CI-7") a/k/a J.D. was employed by Serono as a Drug Rep for Serostim from 2013 until 2014. His territory was the State of Florida.

- Confidential Interviewee #8 ("CI-8") a/k/a P.G. was employed by Serono as a Drug Rep and Sales Manager for Serostim from 2007 until 2013. Her territory was the west coast of the United States.

- Confidential Interviewee #9 ("CI-9") a/k/a S.P. was employed by McKesson as a Telephonic Reimbursement Specialist for Serostim and Saizen from 2011 until 2015.

- Confidential Interviewee #10 ("CI-10") a/k/a D.A. was employed by Serono as a Drug Rep for Saizen from 2010 until 2012. His territory was Seattle, WA and the surrounding area.

THE FRAUDULENT SCHEMES

81. Based on Relator's investigation, there is overwhelming evidence that Serono, with substantial assistance from Brightstar, Maxim, Integrity, and Proherant engaged in a complex, multi-part scheme that involved the payment of kickbacks to prescribers for the purpose of increasing the Covered Drugs prescriptions. Serono violated the AKS during the last

decade because it gave tens of millions of dollars in direct and indirect "in kind" remuneration to gain control of hundreds of millions of dollars in market share for Serono drugs. Serono engaged in three separate remunerative schemes – each violated the AKS.

82. The first scheme involves Serono, Brightstar, Maxim, Integrity, and Proherant's Nurse Educators providing free nursing services to doctors as an unlawful "in kind" remuneration to induce recommendations for Serono drugs to patients.[6]

83. The second scheme involves Serono providing an additional form of "in kind"[7] remuneration in the form of "reimbursement support services," or RSS, saving providers thousands of dollars in administrative expenses to induce providers to recommend the Covered Drugs.[8]

84. The third and final scheme involves direct payments by Serono to Brightstar, Maxim, Integrity, and Proherant's Nurse Educators to recommend and sell the Covered Drugs as the treatments of choice.[9]

85. We describe Defendants' unlawful conduct in greater detail below.

Scheme One: Providing Free Nurse Educator Services to Physicians as a Quid Pro Quo for Referrals

86. In its first scheme, Serono offered free nurse education and patient management services to providers in exchange for those providers recommending Covered Drugs over competitors' drugs. Serono, through Brightstar, Maxim, Integrity, and Proherant, began pitching "solutions" to the particular needs and challenges that providers face in managing certain patients.

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[6] This first scheme is detailed in Section IV.B below.
[7] 42 U.S.C. § 1320(b). Illegal remuneration includes "in kind" remuneration.
[8] This second scheme is detailed in Section IV.C below.
[9] This third scheme is detailed in Section IV.E below.

87. HIV and hormone deficient patients can be complex, typically require multiple medications, and often require extra office, training, time and resources to manage their disease. Most providers typically allocate between 10 to 15 minutes to see routine patients, despite patients requiring much more time to manage. Serono learned that only the largest and most profitable clinics and providers could afford to employ and pay for their own Nurse Educators to manage their patients. Smaller and less profitable providers were very unlikely to incur the cost of a Nurse Educator, which cost $50,000 to $100,000 in annual salary, or an average hourly wage of $40.00 per hour.

88. Based upon this information, Serono developed a marketing strategy based upon furnishing Nurse Educators, usually through McKesson, Brightstar, Maxim, Integrity, and Proherant, to providers to induce those providers to choose the Covered Drugs over competing drugs. Serono's Nurse Educator services ranged from: (i) assisting with practice efficiency; (ii) training on care; (iii) eliminating the administrative expense of teaching patients self-injections; and (iv) being "on call" to answer a patients' care questions.

89. The CIs confirm they taught patients to *self*-inject, and they did not administer the injections.[10] Serostim and Saizen administration is *not* a billable event under Medicare or Medicaid.[11] Patient self-injection training is enormously time consuming for a busy practice as CIs confirm the patient education takes between forty-five minutes and two hours. As discussed in more detail below, providers derive most of their revenue from 15, 30, and 45-minute units of

[10] Patients were trained on using either the subcutaneous (i.e. under the skin) device or the "Cool Click" device, which uses a pressure system to deliver the medication into the skin.

[11] Serostim and Saizen are listed under the Center for Medicare and Medicaid Services' Self-Administered Drug ("SAD") Exclusion list. This list identifies drugs whose administration is not covered under Medicare or Medicaid as the drug is considered self-administered. The SAD Exclusion list can be found here: https://www.cms.gov/medicare-coverage-database/reports/sad-exclusion-list-report.aspx?bc=AQAAAAAAAAAAAA%3D%3D&

service provided to patients during office visits. The technical term for an office visit is "evaluation-and-management services" or "E/M" for short. In 2012, the most commonly billed Medicare physician service was the $70 "doctor office visit" for a 15-minute consultation, closely followed by the $100 "doctor office visit" for a 30-minute consultation. As you can see, the more time a provider spends with a patient, the less money the provider receives per unit of time; the provider only receives an additional $30 for the 30-minute consultation as compared to the $70 15-minute consultation. The additional 15 minutes is reimbursed at *less than half* the rate of the first 15 minutes. Financially speaking, it's in the provider's best interest to see more patients as opposed to spending a lot of time with only a few patients. Therefore, in order for providers to teach patients how to self-inject, they have to accept lower reimbursed rates for the additional time spent with patients--that is, without the services of Serono's Nurse Educators. Of course, in typical quid pro quo fashion, in order for providers be given these Nurse Educator support services, providers would have to "support" (i.e., write prescriptions for) Serono drugs.

90. In theory and substance, the Nurse Educators are free employees given to providers. The quid pro quo Nurse Educators and RSS for Serostim are marketed using the term, the "AXIS Center," while the Nurse Educators and RSS for Saizen are marketed using the term "Connections for Growth," in reference to Saizen being a growth hormone therapy. Serono even promotes "In-home or in-office injection training" on their Serostim website,[12] and "personal device training" on their Saizen website.[13]

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[12] Serostim Patient Support, https://serostim.com/patient-support-services/, (last visited April 19, 2018)

[13] Saizen Patient Support, http://www.saizenus.com/getting-help/patient-support-services/, (last visited April 19, 2018)

91. The AXIS Center and Connections for Growth programs have been ongoing for at least the past eight years. Serostim Nurse Educators would see patients generally in their own home or sometimes at the provider's office. The self-administration training could take anywhere from forty-five minutes to two hours. CI-1, a Serostim Nurse Educator, explained that roughly 20% of patients require more than one training. CI-3, a Serostim Nurse Educator, alone educated roughly four patients per month for three years, and performed *four or five* follow up visits with each patient in a two-week period. She stated the follow-ups were "built into it." CI-8, a Drug Rep, summarized the entire quid pro quo scheme by saying "a doctor would not want to prescribe the drug [Serostim] if we didn't have that support [Nurse Education]." The Saizen program is similar to the Serostim program, and some of the Serostim Nurse Educators, such as CI-5, also taught patients to self-inject Saizen.

92. Thus, rather than promoting and marketing Serono drugs based upon patient outcomes and efficacy, Serono added unlawful incentives (i.e., the Nurse Education service) for providers to recommend Serono drugs over competing drugs to patients. Serono knew that the program would reduce administrative costs for providers, and, consequently, providers would likely "push" patients to join the program, and drive sales of Serono drugs.

93. Further, as recently as December 2016, the Department of Health and Human Services ("HHS-OIG") issued a 234 page document[14] regarding AKS safe harbor exceptions to *beneficiaries*. In this document, HHS-OIG explicitly stated that "education or information alone would not qualify as "remuneration" at all [to beneficiaries]."[15]

94. Interestingly, in this document HHS-OIG flatly rejected a request to allow a "parallel" AKS safe harbor for "remuneration to *providers*" (emphasis added) for "remote patient

[14] 81 Fed. Reg. 88,368 (December 7, 2016)
[15] *Id.* at 88,397

monitoring" and "adherence support," both seem to be references to Nurse Educator services.[16] It appears a commenter was attempting to obtain favorable language from HHS-OIG regarding Nurse Educator services to providers without alerting HHS-OIG of the already in-use practice of supplying providers with Nurse Educators. HHS-OIG flatly rejected the notion, "For a number of reasons...we decline to create a parallel safe harbor in this final rule...this exception applies only to remuneration offered to beneficiaries, and we believe that *the risk of fraud and abuse would be too high to generally protect remuneration offered to providers or suppliers under these standards.*"[17] (emphasis added)

95. The interviewees confirm that the Nurse Educator services were a significant tangible value to a provider that saved staff time, money and resources and "eliminate[d] an expense that [the provider] would have otherwise incurred"[18] if they employed a Nurse Educator. Not surprisingly, Serono saw their drug sales increase whenever and wherever a Nurse Educator supported a provider.[19]

Nurse Educator Services were Offered to Providers in True Quid Pro Quo Fashion

96. The Confidential Interviewees confirm Serono Drug Reps were trained to encourage providers to "off-load" their patients to the Nurse Educators for management. CI-8, a Serostim Drug Rep, explained, "one of the biggest objections was the [self] injection, and having a nurse educator show them [patients] how to actually administer the drug... so the training around that would ride all to increasing a physician's comfort level with prescribing a drug

[16] *Id.* at 88,398

[17] *Id.* at 88,398

[18] Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003) Section II (2) suspect remuneration as it "eliminate[d] an expense that the physician would have otherwise incurred (i.e., have independent value to the physician)".

[19] The tracking data from the Nurse Educator would reveal the time, place and service provided which could then be correlated with subsequent sales.

[Serostim] for any particular patient." CI-8 then explained her offer for Nurse Educator services, she said "...there's very little time required on your [provider's] part, your staff's part, so really its nothing off your back." CI-8 then explained the precise reason why Serono offers Nurse Education services, "the other products [competitors] were a lot easier to use they didn't need nurse educators, so it was okay if you [providers] want to use our product [Serostim] we're going to give you the support around the [self] injection piece, around the administration piece, that you don't need with these other drugs."

97. CI-6, another Serostim Drug Rep, explained "...they [providers] want to use your drugs, but they see that as a commitment of time and money because their office has to deal with it [self-injection training]. So if you're able to put this in a 'This is not gonna be a burden on your staff,' that's a big selling point these days. Time is a huge – time saving is a huge benefit if you can use the nurse educators in that role and sell it on that – sell them [providers] on that, in that concept of saving time."

98. CI-7, another Drug Rep, concurred that Nurse Educator services helped him promote Serostim. He said his message included "...[the] opportunity to have someone dedicated to answering your [providers'] questions or providing support services specifically to the patient on that very narrow disease state or therapy as opposed to having the patient calling the office, and that way the staff is not having to deal with those requests and questions whereas the nurse educator can be solely devoted to that particular patient if they have any issues arise."

99. Similarly, CI-10, a Saizen Drug Rep, explained his offer of Nurse Educator Services. He said, "How it's a resource – it takes time away from their [providers'] nurses, their staff, from themselves teaching how to use the drug... that's something the nurse [educator] will

come and do... in our case it differentiated us from the other companies where we provide that extra service..."

Nurse Educator Patient Management

100. Serono's Nurse Educator patient trainings were held in one-on-one sessions generally in the patient's home or sometimes at the provider's office. The initial sessions last anywhere from forty-five minutes to two hours. A Nurse Educator is alerted to a one-on-one new patient training by their employer, one of the third-party companies. The Nurse Educator then calls the patient and arranges for a meeting in the patient's home.

101. CI-2, a Serostim Nurse Educator, explained his education to patients. He said:

> ...basically just giving them an overview of the equipment. So, the medical device, the medications, and then from there I'd give them a demonstration. My demonstration on how to set up the medication to give the injection. Then from that point watching the patient show back the demonstration, and then practice the injection that would involve a little practice square to do the injection, and then after that w*atching the patient self-administer the medication.*

(emphasis added) CI-2 also confirmed his services saved providers time.

102. CI-1, a Serostim Nurse Educator, explained how Nurse Educator services save providers time and money. She said "...because [providers] not having to provide that [injection training] in their office so they're able to turn over their patient visit time instead of taking an hour for educational time...The patient doesn't have to come to the office, therefore, you don't have the overhead to have to keep an office. You don't have the overhead to have a trained nurse [educator]." CI-1 further explained that the patients have her cell phone number.

103. CI-3, a Serostim Nurse Educator, explained why her services were a tangible benefit to providers by stating:

> I think that it saves time with repeat appointments with patients that keep coming back because they can't do it [self-injection]. I have been out to homes, like I said multiple times, where a patient doesn't get it versus that patient going back to a provider who doesn't have that kind of availability to keep seeing the patient.

104. CI-3 also made "four or five" follow-up visits to patients, she said "I had to keep going back extra because the patients were having trouble with actually squeezing the trigger so I had to keep going back..."

105. CI-4, a Serostim Nurse Educator, explained the patient education. She said "I go there, do the training, *watch them give themselves the first injection*..." (emphasis added) CI-4 then explained how services saved providers time. She said:

> Because the client [patient] would have to come back and forth [to the office], they have to come in, take the nurses'... time with other patients...Because their clients [providers' patients] also would be able to call me if he had trouble with giving [t]his injection... I'd spend an hour with him on the phone...the patients themselves they are too much a nervous wreck...they have tons of questions...

106. CI-4 also explained follow-up visits by saying "...the next day I go back for another re-visit... It's very short. Maybe less than an hour because basically I'm going there just to watch them demonstrate that they know how to do it." CI-4 confirmed patients have her cell

phone number and call her with questions; "...I usually let them call me a couple of times if they have a question..."

107. CI-5, a Nurse Educator for both Serostim and Saizen, first explained the benefit to providers for her Serostim Nurse Educator services. She said "It cut down on the calls that they'd [providers would] get. If they [patients] knew that they had somebody to come out and train them, or somebody they could call on a little bit afterwards. I think that it saved them [providers] the headache..." Similarly, CI-5 also specifically addressed how her Nurse Educator services were a benefit to Saizen prescribers. She said, "...somebody with experience [a Nurse Educator] is going to go and sit down with them [providers' patients] ...they're [patients are] calling the nurse trainer [educator] on their phone instead of the doctor's office. It's definitely going to save them [providers] time." CI-10, a Saizen Drug Rep, estimated that 70% of the Saizen prescribers utilized the Nurse Educator services.

108. CI-1, CI-3, and CI-5 also discussed how they helped patients overcome "needle phobia" where patients are afraid to inject themselves. CI-5 explained, "...injection therapy can kind of be scary, and some of these people have never done that before...So, you have the added learning curve for having a device. I think a lot – it would have been out of the question for a lot of clients [patients] to even consider doing something like that if they didn't have that one on one [Nurse Educator] support..."

109. CI-6, a Serostim Drug Rep, discussed the Nurse Educators' value to providers by saying

> The nurses that can interact with patients is a benefit all the way around, and the office not having to spend time with a patient, so they're – you know, they're happy about it...they've [Nurse Educators have] built a

> personal relationship with the patient and make sure that they're staying compliant with their medications, that if they have any questions, any issues, especially with injectables, there's a lot of needle phobia that a nurse [educator] from your company can help patients work through...a lot of times these patients with the needle phobias need above and beyond nursing help or are pretty cranky, you know, they want to complaint a lot, and just not – not all of them, but a lot of them are just not patients that are fun to deal with. So having – somebody else having to do it is something they [providers] like.

110. CI-7, a Serostim Drug Rep, also explained the Nurse Educators' value to providers. He said "...the opportunity to have a nurse educator in support of the patient I think was *influential sometimes in helping the physician choose a therapy.*" (emphasis added) He continued "...it's minimizing the impact on staff..." Further, CI-7 estimated that 70% of providers who prescribed Serostim also utilized the Nurse Educator services.

111. CI-8, a Serostim Drug Rep, also explained the value to providers by saying:

> ...its like having an extra staff member to help them with injection, with questions because often a patient would have their [Nurse Educator's] phone number, and now they had a question about the injection instead of contacting the nurse or the doctor at the office, they would contact the nurse educator. So here it came down to a very useful time, and not straining the offices time... and often they can have the nurse [educator] come back, and reeducate... it basically took the physician and his staff out of the picture.

112. CI-8 summed up the quid pro quo of Nurse Educator services by saying "...a doctor would not want to prescribe the drug [Serostim] if we didn't have that [Nurse Educator] support." She continued, "...it was the drug [Serostim] plus the service...and everybody wants that in order to prescribe the drug they want to know that you're going to be supporting them in a way that keeps their patients from complaining..."

113. As the foregoing demonstrates, Serono has created a tangible value proposition to dangle as an inducement to the provider: the services of a Nurse Educator to any and all Serono drug patients. In other words, a physician can reduce the time or cost required to treat a patient if he or she gets that patient on Serono drugs. This frees the provider to see other patients, and increases profitability. Under this program, a provider can eliminate the time and expense of managing a patient each time a provider prescribed the Covered Drugs and accepted the services from a Nurse Educator. Further, the more a provider prescribed the Covered Drugs, as opposed to a competitor drug without these services, the more time and cost a provider would save. Thus, Serono, through the services from a Nurse Educator, enabled the provider to "eliminate an expense that [the provider] would have otherwise incurred" if they directly employed the Nurse Educator or provided the services to the patients themselves. These incentives are in return for providers recommending the Covered Drugs to patients. This quid pro quo of Nurse Educator services for recommendations of the Covered Drugs is a clear violation of the AKS.

Scheme Two: Reimbursement Support Services as an Inducement

114. In addition to the scheme outlined above, Serono offered an additional remuneration to induce recommendations of the Covered Drugs over competing drugs. This remuneration was targeted at doctors who were likely to treat patients in disease states that Serono made drugs and, more importantly, those providers' staff who manage the administrative

tasks on behalf of the doctors. The remuneration was a tangible "in kind" benefit that greatly reduced, and in some instances eliminated, providers' administrative costs related to prescribing the Covered Drugs. Serono referred to this remuneration as coverage determination and/or reimbursement support services, but in practice, the services were intended to induce providers to choose the Covered Drugs over a competitor's drugs.[20]

115. Serono hired and trained, through McKesson, dozens of skilled workers to provide free reimbursement support services, including patient insurance benefit verifications services, patient prior authorization services and coverage appeals (collectively, "RSS"). McKesson touts their "Reimbursement and Access Services Solution Center" on their website.[21] RSS personnel work with providers to help identify drug coverage and out-of-pocket costs for Serono medications. Serono's Drug Reps marketed RSS when detailing the Covered Drugs to increase the likelihood that prescribers would prescribe Serono drugs. Put simply, in exchange for prescribing the Covered Drugs, Serono would assume the providers' administrative responsibilities and costs associated with starting a patient on the Covered Drugs. The more a provider prescribed the Covered Drugs as a percentage of its overall prescription volume, the greater the savings and profits to the practice, as time and money spent on handling RSS for the Covered Drugs would now fall on Serono. As detailed below, Serono's RSS were the "carrot" (remuneration) dangled to induce providers to prescribe the Covered Drugs to their patients.

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[20] Reimbursement Support Services not only reduces a cost the providers, it also increases the cost of the drugs, Serono drugs, since Serono has to employ staff and facilities to perform the support services.

[21] McKesson RSS, http://www.mckesson.com/manufacturers/pharmaceuticals/oncology-and-specialty-pharmaceutical-services/reimbursement-and-access-services-solution-center/, (last visited April 19, 2018)

Reimbursement Support and Coverage Determination Services are a Tangible Benefit to Providers

116. RSS are a great value to providers because these services reduce, and in some instances eliminate, the administrative costs associated with prescribing drugs. These services increase profitability for physicians, particularly for "office-based" providers because those providers derive most of their revenue from 15, 30, and 45-minute units of service provided to patients during office visits. The technical term for an office visit is "evaluation-and-management services" or "E/M" for short. In 2012, the most commonly billed Medicare physician service was the $70 "doctor office visit" for a 15-minute consultation, closely followed by the $100 "doctor office visit" for a 30-minute consultation. Medicare pays over $11 billion each year for E/M services alone. Medicaid and private insurers also pay billions each year.

117. When an office-based provider receives payment for an E/M service, part of the payment is intended to compensate the provider for medical care given *and* administrative tasks associated with that patient's care. For example, if a provider receives $50 for an E/M service, a portion of that $50 is intended to compensate the provider for the administrative tasks inherent in managing that patient's care. These tasks include determining the patients prescription drug insurance benefit verifications ("Verifications"), determining if the drug is on the formulary lists and tiers, seeking a coverage determination, determining co-pays and deductibles and telephone calls to patients, responding to patient complaints, returning messages and faxes, handling prescription refill requests and, where necessary, obtaining "prior authorizations"[22] in addition

[22] A study of 12 primary care practices published in the Journal of the American Board of Family Medicine put the mean annual projected cost per full-time equivalent physician for prior authorization activities between $2,161 and $3,430. The study's authors concluded that "preauthorization is a measurable burden on physician and staff time." *See, The Impact of Prior Authorization Requirements on Primary Care Physicians' Offices: Report of Two Parallel Network Studies*, Christopher P. Morley, PhD, David J. Badolato, MD, John Hickner, MD, MSc,

to managing the resulting paper trail.[23] Despite these enormous administrative costs and expenses,[24] office-based providers are not permitted to directly charge patients a fee for any of these services pursuant to the payer-physician contract which pays for these services indirectly through the E/M unit charge.

118. Since a provider's E/M reimbursement for each office visit is fixed per unit, providers are continuously seeking ways to combat and reduce overhead costs and expenses in order to earn more profit from each E/M unit billed. One way to do so is to reduce the administrative costs associated with prescribing drugs. If a provider can reduce this cost, each E/M unit will be more profitable. These economics have a direct impact on a providers' prescribing behavior. Providers are less likely to prescribe a drug that imposes an undue burden on support staff because this decreases profitability by requiring more staff and/or reducing the number of patients that can be seen in a day. Conversely, a provider is much more likely to prescribe a drug if it can be prescribed with little or no administrative burden. Thus, the provider's relative cost and burden in prescribing one company's drug when compared to

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and John W. Epling, MD, MSEd J Am Board Fam Med January-February 2013 vol. 26 no. 1 93-95

[23] In 2006, primary care providers spent a mean of 1.1 hours per week on authorizations, primary care nursing staffs spent 13.1 hours, and primary care clerical staff spent 5.6 hours, according to a 2009 study published in Health Affairs. The study estimated overall costs to the healthcare system of all practice interactions with health plans was between $23 billion and $31 billion annually. Health Aff (Millwood). 2009 Jul-Aug;28(4):w533-43. doi: 10.1377/hlthaff.28.4.w533. Epub 2009 May 14.

[24] A 2011 study published in Health Affairs found that providers spend an annual average of nearly $83,000 of overhead staff time and cost associated with coverage issues plans. That means the total cost to physicians for prior authorizations is around $69 billion annually. With approximately 835,000 physicians practicing in the nation, that represents 868.4 million hours given over annually to this administrative task—not counting other staff members' time. Health Aff (Millwood). 2009 Jul-Aug;28(4):w533-43. doi: 10.1377/hlthaff.28.4.w533. Epub 200 May 14.

another company's drug can directly influence which drug a provider will recommend to a patient.

119. These factors are not lost on pharmaceutical manufacturers like Serono. As such, over at least the last six years, Serono, through McKesson, developed a concierge of RSS that are marketed to providers along with Covered Drugs in order to increase the likelihood that providers choose to recommend Covered Drugs. While these services cost millions of dollars to provide, Serono readily incurred this expense, knowing that these services would act as a powerful inducement to providers to recommend Covered Drugs over a competitor's drugs.

Serono's RSS sales Pitch to Providers

120. Serono Drug reps' pitch to providers was essentially as follows:

> Dear Part D Doctor: If you prescribe our drug (i.e., "recommend" the patient use our drug), we will give you the services and resources of a full reimbursement support team to manage the administrative tasks associated with prescribing the drug, including in-person support. This service will save you the cost and expenses normally associated with managing a patient's prescription and make your practice more profitable.

121. This value proposition was a powerful tool in the hands of the Serono Drug Reps and Nurse Educators, and used to induce providers to recommend the Covered Drugs. CI-6, a Serostim Drug Rep, explained his pitch to providers, "This'll take the burden off of your staff, doctor…We know this product. We know what is needed for this product..." CI-7, a Drug Rep, had the same pitch, "…to ease the burden on both the office staff and on the patient…"

122. CI-8, a Serostim Drug Rep, summarized the exact reason why these quid pro quo RSS were offered to providers. She said, "Without the reimbursement support many scripts would not have been written." CI-8 further explained her pitch to providers, "It's not going to make another job for one of your staff people because we have got people that are skilled in it and could do it for you." She continued, "This was a huge benefit and its absolutely needed, and

if you go in there with that benefit, that service [RSS], then you will definitely get more traction in that office, *without it you might as well kiss your sale good bye.*" (emphasis added)

123. Further, CI-10, a Saizen Drug Rep, agreed that one of his goals as a Drug Rep was to get providers and their staff to utilize Serono's RSS.

Serono Drugs' RSS are a Tangible Value to Providers

Benefit Verification and Coverage Determine Services

124. Because many drugs are expensive, most, if not all, patients cannot afford therapy unless it is covered by insurance. As a result, successfully starting patients on a drug therapy typically requires an initial determination to verify whether the patient has prescription drug coverage to cover the cost of the drug. This process is called an insurance or benefit verification. For most providers, the Verification of a patient is performed by staff at the expense of the practice. It can take multiple calls and over an hour just to determine the nature and extent of the patient coverage. However, if the provider recommends a Covered Drug, the Verification task is handled by Serono's staff, through McKesson, rather than the provider's staff.

125. Each day, the RSS team receives electronic and fax prescription requests from providers. Each request is immediately forwarded to the verification specialists who will perform the Verification process for the provider. The verification specialist verifies the patients' primary and secondary insurance benefits (i.e., private insurance, Medicare, Tricare, and/or Medicaid), and contacts that insurer (either on the phone or through an electronic information exchange) to verify the nature and extent of the patient's coverage. In cases of Medicare and Medicaid, this is called a "coverage determination." For Medicare patients, a coverage determination is

particularly cumbersome and time consuming given the complexity of many Part D plans that have four coverage phases.[25]

126. Nearly all providers who choose the Covered Drugs also accept Serono's offer to perform the RSS, including Verifications. CI-6, a Serostim Drug rep, estimated that *80%* of providers utilize RSS, while CI-7, another Serostim Drug Rep, estimated that *100%* of providers utilize RSS. CI-7 said "...*every prescription* went through that third-party hub [McKesson] and that was part of how the prescriptions were processed." (emphasis added) CI-9, reimbursement personnel for both Serostim and Saizen, concurred with a provider utilization estimate of *95%*. These services have real value, because without them, physicians must use their own staff at their own cost, or outsource this service, and pay a $50 to $80 per transaction fee. Serono gives providers a means to "outsource" this function without any direct or indirect cost to the provider – but *only if* the provider prescribes the Covered Drugs.

127. Another RSS given by Serono is prior authorization services. Many insurance carriers require a provider to obtain a prior authorization before prescribing medications. Further, if a medication receives an authorization, that authorization may only be valid for a limited time, such as for one year or one month. After that, the provider must start the prior authorization process over again. For the most expensive Covered Drugs, that almost always require prior authorizations from a patients' drug coverage plan, these services are particularly valuable for providers. In fact, the cumbersome and reviled paperwork associated with certain drugs may, in many cases, result in a provider choosing to write a cheaper competitor medication that does not

[25] The (1) deductible phase, where a patient pays 100% for drug costs until the deductible amount; (2) initial coverage limit phase, where a patient pays a percentage of the cost depending on the carrier and the drug's formulary position; (3) coverage gap or "donut hole" phase, where patients pay 45% of the cost for brand-name drugs and 65% of the cost for generic drugs in 2015; and (4) catastrophic coverage phase, where a patient pays either 5% of the covered drug cost or $2.65 for generics and $6.60 for brand name drugs in 2015.

require a prior authorization – which in many instances is the desired result of the Part D carriers because it uses the prior authorization process as means to contain costs associated with highly reimbursed drugs. Thus, if a provider wants to recommend one of Serono's more expensive drugs, the Part D carriers require the provider to go through the administrative process and "make the case" for prescribing the drug over a cheaper drug. Under the Serono procedure outlined above, it is *Serono*, through McKesson, more than the physician, "making the case" for the drug.

128. In addition to working on the initial authorization, if a patient's carrier denies coverage for the Covered Drugs or denies the authorization request, Serono also provides a service to appeal that adverse determination and ultimately achieve a reversal of the adverse determination.

129. The process of obtaining a prior authorization and/or appealing a denial requires direct medical input from the provider regarding a patient's medical necessity for a drug and specialized knowledge from the provider's staff about each carrier's unique prior authorization and coverage criteria. Although these steps ordinarily require time and expertise from the provider and staff, like Verifications, providers are not permitted to charge a fee to patients for obtaining an authorization pursuant to payor contracts that pay for this service in the E/M unit payment.

130. CI's confirm that RSS are a valuable, tangible benefit to the providers. CI-6, a Serostim Drug Rep, explained the value of Verifications. He said "...it takes the burden off of the staff to verify a patient's insurance. It's just – you know, it's just the – a task that they don't have to do and they're happy about that." CI-6 then explained how the prior authorization process is a benefit to providers, and how it's also a benefit to *Serono*. He said, "...prior

authorizations can be a real headache…they [providers] shell out prior authorizations for just tons of products and they often leave things out of prior authorizations, or don't provide the right support for those, so they end up getting it back. And that's a very frustrating and *a business killing situation…*" (emphasis added) CI-6 summed up the entire quid pro quo RSS scheme by saying, "You know, if they've [providers] got to run up against a bunch of barriers, or issues, or problems, then that – they don't want that. So, anything you can do to help them with that, you know, it's gonna make everybody happier and, and *more prescriptions, obviously.*" (emphasis added)

131. CI-7, another Serostim Drug Rep, explained RSS' value to providers by saying "…it frees up time they can better spend on patient care in the office, it eliminates the opportunity for errors, it increases efficiency…" He concurred with CI-6, and explained how prior authorization services helped both providers *and Serono*. He said:

> …when you have a reimbursement member working with a member of [the provider's] staff to do the prior authorization you have *a much greater chance of that prior authorization going through*…because it increases accuracy, gives someone the opportunity to answer questions prior to submission and possibly *will reduce the number of appeals* that then have to be filed.

(emphasis added)

132. Regarding appeals, CI-7 summarized the *exact* reason why Serono, through McKesson, wants to be a part of the reimbursement process. He said "…when the reimbursement specialists can focus on the specific reason for denial then the specific

requirements for the appeal...They can be instrumental in giving a properly vetted appeal put together...*it increases the likelihood that it will be approved.*" (emphasis added)

133. CI-8, another Serostim Drug Rep, concurred with CI-6 and CI-7. She summarized the quid pro quo RSS scheme in one sentence; "Without the reimbursement support many scripts would not have been written." She continued, "...reimbursement was critical because the doctor's offices didn't want to do the work... most new offices or offices that were very busy didn't want to have somebody doing that work so for us to take that burden off of them was a huge benefit... This was a huge benefit and its absolutely needed, and if you go in there with that benefit that service then you will definitely get more traction in that office, without it you might as well kiss your sale good bye." Further, CI-10, a Saizen Drug Rep, also agreed that Serono's RSS helps providers' "bottom line."

134. CI-9, reimbursement personnel for both Serostim and Saizen, explained some of her day-to-day activities. She said "We would get a statement on medical necessity from the physician requesting benefit verification, and prior authorization for those medications, so Serostim, and Saizen, for a patient in their office..." CI-9 said she performed "about 10" Verifications per day. She continued, "We would fax that information [from the insurance Verification] over to the physician's office, and at the end of our investigation if we require the prior authorization we would call the patient, and let them know what their benefit was...out of pocket, coinsurance, copay, for that medication..."

135. CI-9 then explained the prior authorization process, "To get it started would be about 15-20 minutes depending on how long you are on with the [Insurance Company's] prior authorization department, it would take another day or two... we get the information back from

the physician, and then another day or two for the insurance company to review it, and approve it."

136. She continued regarding coverage appeals, "Once we...determine that the prior authorization has been denied we would call to confirm the denial reason, ask if it could be resubmitted as a reconsideration with the information that was lacking... The appeals process is a lot more intricate, and complicated where it takes more time...Something that I think is not on a top priority for the physician to do."

137. CI-9 summarized the quid pro quo RSS scheme by saying, "Once the doctor sees results with that reimbursement support they are going to more than likely *send more prescriptions, write more prescription for that certain medication for their patients.*" (emphasis added)

138. For many years, Serono trained personnel have handled nearly all prior authorizations and appeals needed for the most expensive Covered Drugs prescriptions, giving a clear advantage *and* tangible financial incentive to physicians choosing to prescribe the Covered Drugs over competitors. Like with the Nurse Educators, Serono, through McKesson, will have detailed data regarding the time, place, amount and other particularized details of each time it provided a reimbursement support service for a Covered Drug prescriber. The number of instances this service was provided will obviously directly correlate with the number of Covered Drugs prescriptions. Although correlation is not always causation, here the causal link is particularly strong as many providers use the reimbursement support services, rather than handling the tasks themselves.

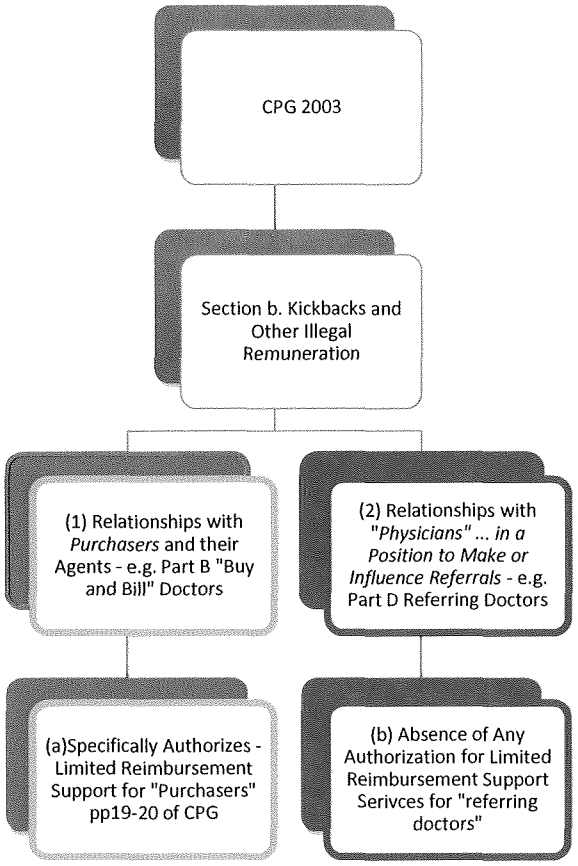
OIG and Reimbursement Support Services

139. The AKS specifically defines remuneration to include "services for free." If the services are services that the physician would have otherwise provided, but now receives from a third party to induce referrals or recommendations, this is a kickback that violates the AKS.

140. For decades, the HHS-OIG has recognized that support services that drug companies offer to induce providers to recommend drugs can easily violate the AKS. In 2003, for example, the HHS-OIG undertook a comprehensive analysis of this and other questionable marketing practices and published its findings in the "Compliance Program Guidance for Pharmaceutical Manufacturers" ("CPG").[26] The CPG publication is a comprehensive and detailed document covering a myriad of transactional scenarios in the pharmaceutical industry which offers clear and detailed rules, many of which Serono has violated here.

141. In the CPG section entitled "Kickbacks and Other Illegal Remuneration," (the "AKS Section") the HHS-OIG analyzes the AKS and the "constraints it places on the marketing and promotion of [drugs] reimbursable by the federal health care programs," and specifically identifies "Key Areas of Potential Risk" (the "Potential Risk Section"). Within the Potential Risk section, the HHS-OIG analyzes the potential risks involved with two separate groups of "relationship" partners, each of whom transact business with the pharmaceutical industry. These two groups are identified in the chart below:

[26] 68 Fed. Reg. 23,731 (May 5, 2003) (noting that the "guidance provides the ***OIG's views on the fundamental elements*** of pharmaceutical manufacturer compliance programs and principles . . .") (emphasis added). Notably, this guidance has not been amended or rescinded since its 2003 publishing.



142. The first relationship analyzed is "Purchasers and their Agents" which are partners that purchase drugs from the pharmaceutical manufacturers, including hospitals, nursing homes, pharmacies, *some physicians* and indirect purchasers.[27] The term "some physicians" in this section refers to providers who prescribe Part B (i.e., "buy and bill") drugs. Unlike the providers who prescribe D drugs (i.e., Serono Drugs,), a Part B provider purchases drugs directly from the specialty pharmacy and administers the drug to patients. The provider then bills for the drug and its administration to the patient. For these Part B providers, the HHS-OIG authorizes a drug company to provide limited RSS because these providers must make an initial financial investment in acquiring the drug. The HHS-OIG recognizes that these providers may be reluctant

[27] CPG Section IIB(2)(b)(B)(1)(a)

to make this investment in an expensive drug for fear that it would not be able to recoup the initial outlay in the reimbursement process. Thus, the HHS-OIG strikes a balance between that risk, and the risk posed by reimbursement support and coverage determination services as unlawful inducements, and authorizes limited support services that have no independent value to "buy and bill" providers and other purchasers. Thus, if Serono were only offering limited support services to "buy and bill" Part B providers, the conduct would potentially face less scrutiny by the HHS-OIG.

143. However, as detailed above, Serono, for the last decade, has not been offering RSS to Part B "buy and bill" providers, but instead to providers prescribing Part D drugs to their patients, who are covered in the CPG Potential Risk section entitled "Physicians and Other Persons and Entities in a Position to Make or Influence Referrals."[28] This group is comprised of "persons or entities in a position to refer, order, or prescribe—or influence the referral, ordering, or prescribing of—the manufacturers' [drugs]," and includes the providers who prescribe Serono Drugs. Unlike in the case of the Part B providers, notably absent from this section is any similar language authorizing RSS to Part D providers. Thus, the HHS-OIG specifically chose *not* to permit RSS for these providers, and instead urged close scrutiny:

> Any time a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer's product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals. For example, if goods or services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (i.e., have independent value to the physician), or if items or services are sold to a physician at less than their fair market value, the arrangement may be problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer.[29]

[28] CPG Section IIB(2)(b)(B)(1)(b)

[29] *Id.* That this guidance predates Medicare Part D's 2003 enactment and 2006 effective dates is of no moment because HHS-OIG explicitly provided this guidance "in its effort to

144. Further, while Serono may argue that these services do not harm patients – since it helps the patient get the medication – that notion misses the mark. The patients are not only entitled to the medication, but also independent unfettered medical judgment from the providers who recommend that medication. Serono's conduct impugns that judgment.

145. The most analogous guidance from the HHS-OIG on the provision of services for a physician can be found in the December 19, 1994 special fraud bulletin.[30] In that bulletin, HHS-OIG explained that the placement of a phlebotomist in a doctor's office to collect samples would be remuneration if the phlebotomist performed *any* additional clerical or medical services for the physician: "Where the phlebotomist performs clerical or medical functions not directly related to the collection or processing of laboratory specimens, a strong inference arises that he or she is providing a benefit in return for the physician's referral to the laboratory."[31] [32]

146. The HHS-OIG has issued five advisory opinions that directly and/or indirectly touch on the issue of RSS, and in particular, prior authorization services.[33] In those opinions, the HHS-OIG has highlighted the anti-kickback concerns these arrangements pose. Although the HHS-OIG determined that it would not impose sanctions in those cases, they are *very* distinguishable from the conduct in this matter. These reasons were generally as follows:

147. First, in these cases, the HHS-OIG found the entity who was performing the prior authorization service would not know if it was relieving a physician of this prior authorization

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engage the health care community in preventing and reducing fraud and abuse in health care programs," not just in *parts of* programs, such as Medicare.

[30] This guidance was provided on the Stark Law, but is instructive nonetheless on the issue.

[31] *Id.*

[32] This OIG guidance regarding phlebotomists is also a parallel to Nurse Educator services.

[33] OIG Advisory Opinions 12-10, 08-12, 10-04, 00-10, and 10-13.

responsibility, and it would "occur by chance, not design."[34] Here, by contrast, under Medicare Part D and all prescription benefit plans, it is the provider's responsibility to obtain the prior authorization. Therefore, Serono Drugs' coverage determination, prior authorizations and RSS are, by design, intended to relieve the physician of this responsibility in order to induce to recommend Serono Drugs.

148. Second, in these opinions, the HHS-OIG found (i) there was an absence of any payment to providers; (ii) there was no assurance of pre-authorizations being granted; (iii) the entity providing the service would only pass on medical necessity documents that it receives from doctors; and (iv) the entity would comply with all Federal privacy laws. Here, although there is no direct payment to providers, nor assurance of prior authorizations, Serono is doing far more than acting as a conduit for the prior authorizations. Serono is also performing benefit verifications; coverage determination requests; and appeals. Finally, unlike the servicing entity in the HHS-OIG opinion (i.e., an imaging center that is a healthcare provider) a drug company like Serono is not a covered entity under HIPPA, raising HIPPA privacy issues that were not present in the HHS-OIG advisory opinions.

149. The HHS-OIG also found in these advisory opinions that the entity performing the service acted with "transparency" and had no "ability to influence referrals." It is quite the opposite here, as Serono does not act transparently. Unlike the entity in the opinions, Serono has a direct opportunity to influence a recommendation of their drugs over competitors. Indeed, it is the entire purpose of Serono's RSS to influence a provider's choice of which drug to recommend to a patient.

[34] OIG Advisory Opinion 12-10

150. Another distinguishing feature in the HHS-OIG opinions touching on RSS is that in those cases the HHS-OIG found the entity providing the RSS had what HHS-OIG called a "legitimate" reason for offering the service – i.e., the servicing entity's payments were "at stake" and, as such, found the purpose of the services "wholly distinct from a scheme trying to curry favor with referral sources."[35] By contract, here, Serono does not have a direct reimbursement payment at stake. Serono sells drugs to wholesalers and pharmacies. More importantly, unlike the entity in the HHS-OIG opinion, the purpose of Serono's scheme is not "wholly distinct" from a scheme to curry favor with potential prescribers. Rather, it is the entire purpose of the scheme to curry favor with providers by reducing their overhead costs to induce the provider to recommend their drugs over competitor's drugs. Given the foregoing, in HSA's judgment, the HHS-OIG would have made decidedly different findings and conclusions if the entity requesting to provide the RSS were a drug company like Serono.

151. Finally, in Advisory Opinion 00-10, the HHS-OIG stated it would permit limited RSS provided by a drug company with respect to a pediatric drug. However, a close reading of the facts there demonstrates that there were numerous limiting factors present in 00-10 that are not present here. First, the services offered were "narrowly tailored" to address what the HHS-OIG stated was a "unique access problem." The services were limited to "one product – a new, expensive, prophylactic drug." Finally, and perhaps most importantly, this was a Part B drug, for which the HHS-OIG has permitted limited reimbursement support (as was cited in the opinion). However, the HHS-OIG has never authorized such reimbursement support schemes for providers who are in the position to recommend Part D drugs to patients. Thus, 00-10 will not in any way shield Serono's unlawful RSS scheme.

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[35] *Id.*

152. Thus, as detailed in this section, the HHS-OIG's determining factors in these opinions are not only distinguishable; but the sharp contrast of these factors with Serono's conduct herein strengthens further the case that action in this matter is warranted. Importantly, Serono could have asked the HHS-OIG to review its RSS and its application under the AKS and other HHS-OIG guiding principles. However, Serono, like most other drug companies over the last decade, operates under the principle that it is "better to ask for forgiveness than permission" when deploying these various marketing schemes to promote its drugs. Thus, although Serono will undoubtedly point to these HHS-OIG opinions as providing protection for its provision of reimbursement services, such sanctuary is disingenuous and illusory.

153. Further, the HHS-OIG's AKS concern regarding RSS is reiterated in the PhRMA Code on Interactions with Healthcare Professionals. The PhRMA Code sets forth the standard of conduct for drug companies like Serono and specifically prohibits subsidizing and/or supporting RSS:

> No . . . subsidies, support . . . [or] related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices.

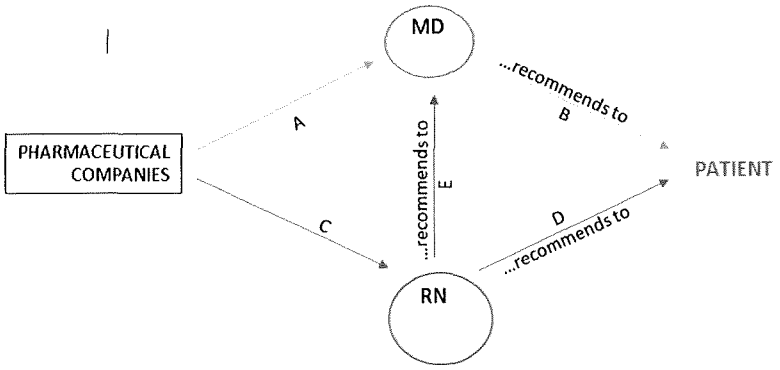
154. Thus, not only does the HHS-OIG find it "problematic" for a drug manufacturer to provide services of value to a prescribing physician because of the AKS, but the PhRMA Code specifically prohibits this type of remuneration.

Scheme Three: White-Coat Marketing by Nurse Educators

Nurse Educators and the AKS

155. Serono contracted with the other named defendants to employ nurses to help promote Serono's drugs. Providers often restrict or deny access to drug reps, but tend to be more willing to meet with healthcare professionals. Accordingly, per the arrangement between Serono

and the other named defendants nurses were deployed to gain access to providers in order to market and promote the Covered Drugs. For illustration purposes, the channel of remuneration in this scheme is illustrated below.[36]



156. Given the Government's success in stamping out the kickbacks outlined in blue, drug companies have pivoted to the model demonstrated by arrows C and D. The remuneration flows to Nurse Educators who, in turn, are recommending the Covered Drugs to providers and patients. However, while the remuneration flows through a different channel, the legal significance remains the same: The conduct violates the AKS.

157. Importantly, the AKS is not limited solely to remuneration to physicians. Instead, the AKS was broadly written to make it illegal for any person who "knowingly and willfully . . . offers or pays any remuneration [(i.e., "anything of value")][37] . . . directly or indirectly . . . in cash or in kind to *any person* to induce such person . . . to purchase . . . *or recommend*

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[36] *See* HHS-OIG Special Fraud Alert, 59 Fed.Reg. 65, 372, 65,376 (Dec. 19, 1994) (explaining the prohibition against drug companies "offer[ing] cash . . . to pharmacies for each time a drug prescription [is] changed from Drug Company B's product to Drug Company A's product.")

[37] *U.S. v. Narco Freedom, Inc.*, 95 F.Supp.3d 747, 756 (S.D.N.Y. 2015) (quoting *Klaczak v. Conol. Med. Transp.*, 458 F.Supp.2d 622, 678 (N.D. Ill. 2006) ("Remuneration, for purposes of the AKS, is defined broadly, meaning 'anything of value'")).

purchasing . . . or ordering any good . . . or item which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1302a-7(b)(2)(B) (emphasis added). The party offering such remuneration may be liable under the AKS even if the recommendation is not the sole purpose of the payment. Regardless of how many legal reasons a payer may contend justify the remuneration, liability will attach provided just *one* purpose of the remuneration is to induce a referral or recommendation.[38] In this case, the interviewees confirm that Serono paid remuneration to Nurse Educators (i.e., hired via a third-party) to recommend the Covered Drugs over competing drugs to patients. Remuneration by a drug company, like Serono, to "white coated" Nurse Educators differs slightly from the traditional form of unlawful remuneration of the past: (arrow A).[39] However, the AKS proscribes the *conduct* (i.e., payment or offer of payment) of "*any person*" in exchange for a recommendation or referral. It is immaterial if the payee receiving the remuneration is a doctor (who writes a patient a prescription) or some other payee such as a nurse, a runner, a patient recruiter, or a "carnival barker" who can recommend by promoting the drug through other means.[40] Thus, while payment to the Nurse Educators differs in some manner because the nurse cannot write a prescription, for purposes of the AKS, that

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[38] HHS-OIG Special Fraud Alert, 59 Fed.Reg. 65, 376 ("If one purpose of any . . . marketing scheme is to induce the provision of a prescription drug item reimbursable by [a Federal health care program] then the criminal anti-kickback statute is implicated."); *see also Narco Freedom*, 94 F.Supp.3d at 759 ("Courts consistently have held that the Government need only prove that 'one purpose' of remuneration is to induce a person to use a service for which payment is made under a federal health care program.").

[39] *See* HHS-OIG Special Fraud Alert, 59 F.R. 65372, 65376 (Dec. 19, 1994) (explaining the prohibition against drug companies "offer[ing] cash . . . to pharmacies for each time a drug prescription [is] changed from Drug Company B's product to Drug Company A's product.")

[40] *See United States v. Polin*, 194 F.3d 863, 866-67 (7th Cir. 1999) (holding that the referral or recommendation cannot come from a physician only, "The different subsections [of the AKS] do not distinguish between physicians and lay-persons."); *United States v. Rogan*, 459 F.Supp.2d 692, 714-15 ("The term 'refer' as used in the [AKS], is not limited to the physician who formally authorizes a particular service.")

distinction is without a material difference – payment to "anyone" results in an AKS violation if part of that payment is to induce a recommendation.

158. Here, it is immaterial whether the Nurse Educator actually writes a Covered Drug prescription for the purposes of the AKS. The AKS makes it unlawful to exchange anything of value for a "referral" or "recommendation."

159. As detailed below, Serono paid *millions* in sum to the third party employed Nurse Educators to refer or recommend the Covered Drugs to patients and drive sales. Thus, Serono, the Nurse Educators' employers, and the Nurse Educators violated the AKS.

Serono's Legal "Fig Leaf:" Disease Education

160. Serono needed a clever and nuanced approach to disguise this marketing strategy. After all, Nurse Educators could not openly appear to act in the role of drug reps for several reasons. One, providers would not allow Nurse Educators' to educate patients if providers knew their true role was marketing. Two, perhaps the biggest obstacle, is that the anti-kickback statute prohibits pharmaceutical companies from paying non-employees (i.e. third parties) to "recommend" its drugs to others as is set forth in the previous section. Finally, the HHS-OIG looks particularly unfavorably the "white coat" marketing. (i.e., utilizing nurses to promote drugs). For those reasons, and more, Serono could not openly admit the Nurse Educators were paid to recommend Serono Drugs.

161. As a result, Serono contrived disease awareness programs that would act as a cover for the Nurse Educators – programs that could make Nurse Educators appear to be functioning distinct and independent from the role of marketing. Serono designated the nurses as "educators" who, instead of being paid to recommend drugs, were now claiming to market and promote free educational services to providers and patients. Although "on paper" the nurses

were called educators, the witnesses all make clear that the Nurse Educators were expected to recommend Serono Drugs to providers and patients.

Serono Trains Nurses in the Tradecraft of Drug Reps

162. Interviewees confirm that Nurse Educators would gain access to providers when Drug Reps could not, and they also confirm that Nurse Educators were influential in keeping patients on Serono Drugs. Further, Serono selectively deployed Nurse Educators to target and gain access to providers and facilities that were identified to generate the greatest sales of the Covered Drugs.

163. CI-6, a Serostim Drug Rep, explained how Nurse Educators gain access to offices. He said "...there's things called Reptrax and Docurep that are blocking our representatives, but sometimes the nurses [Nurse Educators] can get in, being seen as not a salesperson, but an educator. So they're able to break into some of these offices..." CI-6 further stated that the Nurse Educators were well aware of their role in gaining access to facilities. He said "...where they [Nurse Educators] can get in... [they] can come back to you and say 'I got in there. I was able to do this and do this. This is where I need you to come in...'"

164. CI-7, another Serostim Drug Rep, concurred; "...in my experience I've noted some Nurse Educators in some facilities, particularly hospital-based environment[s], have better access...because they are not seen as sales, they are more seen as medical education." Similarly, CI-8, another Serostim Drug Rep, concurred; "...there were few offices where they were harder to get in, and if the physician had [a] quantity of patients, then bringing that Nurse Educator to do an in-traverse [in-service] on the [self-injection] protocol with the nurses in that office...We would often get in..."

165. CI-3, a Serostim Nurse Educator, explained how she gained access to Fort Bragg, North Carolina, the largest military installation in the world by population,[41] with more than 50,000 active duty personnel. She said "...I already had access to the Fort [Fort Bragg] and I was one of the few nurses that did, so I went and did it [an in-service]." She explained, "I was going there to train the nursing staff on how to train the patients to administer the injection." As previously noted, CI-3 works for Integrity, which specializes in nurse staffing for *military* health fairs.

166. The white coat marketing aspect of the strategy was hugely successful as Serono gained the much coveted "access" to providers. After gaining this access under the auspices of an education services, the Nurse Educators (i.e. "white coated" nurses recognized as experts) were in an ideal position to exclusively recommend the Covered Drugs to providers and patients.

167. CI-2, CI-3, CI-4 and CI-5, all Serostim Nurse Educators, said that when "educating" HIV patients, they name Serostim, but do not name competitors. Similarly, CI-5, who is also a Saizen Nurse Educator, would not mention Saizen competitors when "educating" patients with growth hormone deficiency. If their role was truly unbiased "education," then the education sessions would be unbranded, as discussed further in the next section. CI-4 elaborated "...when a pharmaceutical company hires a Nurse Educator, basically what they [Nurse Educators] are saying is they believe our medication is best..."

168. CI-6, a Serostim Drug Rep, explained that one of the *main* functions of Nurse Educators was patient compliance. To say it another way, Nurse Educators were expected to *promote the use of Serono Drugs to patients.* He said "I mean, that's kind of one of the main functions [of Nurse Educators], I would think, is their [patient] compliance. I mean, it's – getting

[41] Fort Bragg, https://en.wikipedia.org/wiki/Fort_Bragg, (last visited April 19, 2018)

a patient on medication, if they're not compliant, it kind of defeats the purpose and it hurts the business." CI-10, a Saizen Drug Rep, also "strongly agree[d]" that Nurse Educators are effective in influencing patients to remain on the Saizen therapy. He said "...because they're [Nurse Educators] there following up with the patient making sure that they're continuing their medication [Saizen]."

169. CI-4, a Serostim Nurse Educator, concurred "The economic benefit [to Serono] is that they [Nurse Educators] serve patients that are probably continue to take their medications, correctly...so obviously economically that's what they want..." CI-5 also agreed.

170. CI-1, a Serostim Nurse Educator, explained that Serono tracked the compliance of patients who were trained by a Nurse Educator. CI-1 said "The pharmaceutical companies, they will come with a string of data to show the compliance of the patients with home health care delivery [Nurse Educators], and then also show the doctor that they wouldn't have to have the overhead cost of a Nurse Educator...So, I think that they [Serono] have a net value that actually rolls over into the positive because of the compliance...from *providers and patients*." (emphasis added) To say it another way, Serono planned for and expected Nurse Educators to *promote the use of Serono Drugs to providers and patients.*

171. CI-8, a Serostim Drug Rep, also confirmed that Serono tracked Nurse Educators' interactions with patients. She said, "...looking at the data you know my rep [Drug Rep] would create spreadsheets with the nurse [Nurse Educator] and we would actually get the data from the patients showing if the patient had actually been trained or not..."

172. CI-6 then explained how Nurse Educators are "influential" in getting sales of Serono Drugs. He said "...a lot of these doctors... rely on their nurse, especially if they've been with them for a long time, to know what they would have given... so, you know, you're kind of

selling to the [provider's] nurses. Nurse Educators can be that great a resource because, like I said, they're both nurse[s] – you know, nurse to nurse is a nice way to go because they can talk about a specific patient…"

Serono and the Third-Party Nurse Educator Employers' Conduct Detailed Above Violates the AKS and No AKS Safe Harbor Applies

173. HHS-OIG has established a clear analytical methodology to determine whether conduct violates the AKS and warrants Government prosecutorial action. There are three separate and distinct steps: (1) whether conduct involves unlawful remuneration under the AKS; (2) whether the conduct is protected under a safe harbor pursuant to 42 C.F.R. § 1001.952; and (3) if conduct is not protected by a safe harbor, whether "other considerations" are present which would warrant action by the Government. That methodology is followed below.

Safe Harbor Exceptions

174. The AKS contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. See 42 U.S.C. § 1320a-7b(b)(3). None of the statutory exceptions or regulatory safe harbors protects Defendants from liability for the conduct alleged herein.

175. The Plaintiff states each has enacted statutes that are parallel to the legislative scheme embodied in the FCA and the AKS.

Additional Considerations

176. For years, HHS-OIG has considered the use of "independent" sales agents for Government-reimbursed healthcare items as suspect:

> Sales agents are in the business of recommending or arranging for the purchase of the items or services they offer for sale on behalf of their principals, typically manufacturers, or other sellers (collectively, "Sellers"). Accordingly, any compensation arrangement between a Seller and an independent sales agent for the purpose of selling health care items

> or services that are directly or indirectly reimbursable by a Federal health care program potentially implicates the anti-kickback statute, irrespective of the methodology used to compensate the agent. Moreover, because such agents are independent contractors, they are less accountable to the Seller than an employee. [42]

177. Following this reasoning, HHS-OIG has list of suspect characteristics of independent sales arrangements:

- Compensation based on percentage of sales;
- Direct billing of Federal health care program by the seller for the item or service sold by the sales agent;
- Direct contact between the sales agent and physicians in a position to order items or services that are then paid for by a federal health care program;
- Direct contact between the sales agent and Federal health care program beneficiaries;
- Use of sales agents who are *healthcare professionals* who are persons in a similar position to exert undue influence on purchasers or patients (emphasis added); *or*
- Marketing items or services that are separately reimbursable by a Federal healthcare program (e.g., items or services not bundled with other items or services exclusively by a DRG payment), whether on the basis of charges or costs. [43]

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[42] OIG Op. 98-10, 1998 WL 35287765, at *3 (Aug. 31, 1998). *See Medicare & State Health Care Programs: Fraud & Abuse: OIG Anti-Kickback Provisions*, 56 Fed. Reg. 35952, 35981 (July 29, 1991) (declining to extend exception to independent contractors "because of the existence of widespread abusive practices by salespersons who are independent contractors"); *Medicare & Medicaid Programs: Fraud & Abuse OIG Anti-Kickback Provisions*, 54 Fed. Reg. 3088, 3093 (Jan. 23, 1989) (declining to broaden the exemption because they "are aware of many examples of abusive practices by sales personnel who are paid as independent contractors").

[43] OIG Op. 98-10, 1998 WL 35287765, at *3 (Aug. 31, 1998) (emphasis added).

178. The more "factors that are present, the greater the scrutiny we ordinarily would give an arrangement."[44]

Notably, here, the Nurse Educator's role and conduct in gaining access and recommending Serono Drugs have nearly all of the characteristics cited by the OIG as potentially suspect:

- The Nurse Educators' incentive compensation is linked to the sales volume of the Covered Drugs;
- The Covered Drugs are ultimately billed to Federal health care programs;
- Nurse Educators were contracted to be in direct contact with thousands of physicians and staff in a position to prescribe the Covered Drugs;
- Nurse Educators were in direct contact with Federal health care program beneficiaries;
- Nurse Educators are healthcare professionals able to exert undue influence on purchasers or patients; *and*
- The Covered Drugs are separately reimbursable by a federal healthcare program.

Thus, the arrangement here is a textbook suspect arrangement and violates the AKS.

179. ***Nurse Educators' Inherent Conflict of Interest.*** Not only does Serono and NE vendor employed NEs treating patients and recommending the Covered Drugs to patients violates the AKS, but it also creates a disturbing conflict of interest between the interest of the NE and the best interest of patients. This conflict can harm patients and vastly increase pharmaceutical spending.

180. In an ethical and medically appropriate nurse-to-patient relationship, a nurse has an absolute fiduciary duty of care to the patient. That duty can and should never be

[44] *Id.* at *4.

compromised - in particular, it should not be compromised by a concurrent allegiance or affiliation with any drug or drug company. Without question, nurses and medical practitioners should make medical decisions based solely upon the best interests of the patient. This is not expected, but is a fundamental principle of our healthcare system. However, during recent years, scholars have pointed to increased promotional spending by pharmaceutical companies on nurses (mostly in the form of small gifts, dinners or drug samples) as creating a serious conflict that justifies a ban or strong limitation to protect patients.[45] The conduct here is *far* beyond gifts and drug samples. The Nurse Educator compensation is derived from Serono. This conflict raises an ethical dilemma for Nurse Educators, whether consciously or subconsciously, which disturbingly manifested in the situations below.[46] All patients have a right to be able to count on a nurse's behavior as a source of valid and uncompromised information – especially when it comes to matters of treatment recommendations; and especially when a patient is suffering from a debilitating disease.

181. The conflict of interest manifests in two related situations, continuity of care[47] and medication adherence. A provider's decision to keep a patient on a certain drug or switch to a competing drug is directly affected by a patient's response to a drug treatment. Here, the Nurse Educators work with patients on an ongoing basis and, as such, are part of the patient's disease

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[45] Nancy J. Crigger, *Pharmaceutical Promotions and Conflict of Interest in Nurse Practitioner's Decision Making: The Undiscovered Country*, 17 J. Am. Academy Nurse Practitioners 207-12 (May 27, 2005).

[46] Judith A. Erlen, *Conflict of Interest – Nurses at Risk!*, 27 Orthopaedic Nursing 135-39 (Mar.-Apr. 2008). Erlen argues that a nurse simply accepting small gifts (such as notepads and promotional items) or listening to a marketing pitch is enough to cloud their judgment and create a conflict of interest. *Id.* at 137. This is a far cry from the situation highlighted here where the nurse *is indirectly employed* by the drug manufacturer.

[47] Continuity of care is concerned with quality of care over time. It is the process by which the patient and his/her physician-led care team are cooperatively involved in ongoing health care management toward the shared goal of high quality, cost-effective medical care.

care team. Further, since the Nurse Educators are observing a patient's clinical response to the Covered Drugs, the Nurse Educator is the conduit through which this clinical data is reported back to the provider upon which a provider is making healthcare decisions on behalf of the patient. Since the Nurse Educators' are being paid, in part, to promote the interests of the drug company, there is a substantial risk that a Nurse Educator will selectively filter important medical information in order to ensure that a patient starts and stays on the Covered Drugs. This risk includes minimizing or concealing adverse reactions, contraindications and side effects.

182. Further, the nurse's medical judgment is severely compromised because, NEs are specifically prohibited from discussing other potential drugs to treat a patient's disease even if those drugs could potentially result in a better outcome. Similarly, the NEs must always discuss a Covered Drug, irrespective of whether, in their judgment, it is the best choice for the patient. Furthermore, the conflict may also result in a NE recommending a Covered Drug despite cheaper alternatives which would result in the same outcome. Finally, the NE is disincentivized to learn and explore other potential treatment options which potentially could contribute to a patient's outcome as any other treatment would potentially have adverse financial effects on the NE.

183. CI-1, CI-2, CI-3, CI-4, and CI-5, all Nurse Educators, stated that they do not mention competitor medications when educating patients. CI-3 further explained the exact reason why a conflict of interest exists, "...nurses are the *most trusted profession.* Number 1 on the list, every single year, so why not just have doctors go out and do that [patient training]? Well, if they are not the most trusted profession. It is well spent money sending out someone [Nurse Educators] that the public already trust[s] to provide training, *it's probably less suspicious*...They understand that nurses are coming from a different place, not necessarily a place of greed, but we are *supposed to be* patient advocates." (emphasis added) CI-4 concurred,

"Because basically again, when a pharmaceutical company hires a Nurse Educator, basically what they are saying is they [Nurse Educators] believe our medication is best and we are going to help you [patients] take the medication..." Similarly, CI-5, also a Saizen Nurse Educator, confirmed she does not mention competitor medications, "not at all."

184. Nurse Educators' inherent conflict of interest also manifests in situations regarding medication adherence. In some situations this may positively affect patient outcomes.[48]

185. CI-6, a Serostim Drug Rep, explained that medication adherence is "...kind of one of the main functions [of a Nurse Educator]..." CI-7 and CI-8, both Serostim Drug Reps, and CI-10, a Saizen Drug Rep, agreed that Nurse Educators keep patients on Serono Drugs. However, keeping patients on Serono Drugs may not be in the patient's best interest. A patient may be better off switching to a more effective drug or a cheaper drug, such as a generic; as previously noted, the cost of Serono Drugs' Nurse Educator services are built-in to the cost of Serono Drugs. By no coincidence, patient compliance also benefits Serono by increasing prescription refills. All of the above highlights the inherent conflict of interest that arises by having drug-company sponsored Nurse Educators treating patients and promoting the Covered Drugs.

The Breadth of Serono's Kickback Scheme

186. The evidence uncovered during Relator's investigation reveals a kickback scheme of truly breathtaking proportions.

187. The scheme encompasses every prescriber that, since 2007 received a visit from a

[48] The fact that Nurse Educator services may have a positive effect on patient outcomes is of no moment here, as even when patients benefit from a prescription tainted by a cash kickback, it does not negate the unlawfulness of the kickback itself.

Nurse Educator that purported to provide "education" concerning treatments for HIV and growth failure.

188. The scheme encompasses every prescriber that, since at least 2013, received Support Services from Serono, McKesson, Brightstar, Maxim, Integrity, and Proherant.

189. The scheme encompasses every prescriber that, since at least 2007, received, directly or indirectly, "free nurse" services that were paid for by Serono.

190. Serono and its co-Defendants profited from the illegal schemes described in this Complaint, and Medicare, Medicaid, TRICARE, and Veteran Administration Healthcare were made to bear the costs.

191. Since at least 2007, Defendants' actions knowingly have caused pharmacies, Part D sponsors, fiscal intermediaries and others to submit millions of dollars in claims to Government programs for the Covered Drugs provided to beneficiaries as a result of Defendants' illegal marketing and quid pro quo arrangements. Those false claims have caused the Government to disburse billions of dollars in reimbursements that were tainted by kickbacks and should not have been paid.

COUNT 1 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE FALSE CLAIMS ACT:
PRESENTING FALSE CLAIMS FOR PAYMENT (31 U.S.C. § 3729(a)(1)(A))

192. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

193. Relators seek relief against Defendants under Section 3729(a)(1)(A) of the FCA, 31 U.S.C. § 3729(a)(1)(A).

194. As a result of Serono offering or paying, and Serono and its co-Defendants, physicians, and other health care professionals soliciting or receiving, kickbacks to purchase, order, or recommend the purchasing or ordering of the Covered Drugs in violation of the federal

AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), Defendants caused false and fraudulent claims for payment to be presented to federal health care programs.

195. Accordingly, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

196. By reason of the false or fraudulent claims that Defendants knowingly caused to be presented to federal health care programs, the United States has been damaged in a substantial amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

COUNT 2 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE FALSE CLAIMS ACT:
USE OF FALSE STATEMENTS (31 U.S.C. § 3729(a)(1)(B))

197. Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.

198. Relators seek relief against Defendants under Section 3729(a)(1)(B) of the FCA, 31 U.S.C. § 3729(a)(1)(B).

199. As a result of Serono offering or paying, and Serono and its co-Defendants, physicians, and other health care professionals soliciting or receiving, kickbacks to purchase, order, or recommend purchasing or ordering the Covered Drugs in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), Defendants knowingly caused pharmacies, PBMs, Part D sponsors, fiscal intermediaries, and others to make false records or statements that were material to getting false or fraudulent claims paid by federal health care programs.

200. More specifically, the pharmacies, PBMs, Part D sponsors, fiscal intermediaries, and others, falsely certified, and/or represented that the reimbursements they sought for the Covered Drugs were in full compliance with applicable federal and state laws prohibiting fraudulent and false reporting, including but not limited to the AKS. Those false certifications,

statements, or representations caused federal health care programs to pay out sums that would not have been paid if those programs had been made aware of the falsity of the certifications, statements, or representations.

201. Accordingly, Defendants caused the use of false records or statements material to false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(B).

202. By reason of these false records or statements, the United States has been damaged in a substantial amount to be determined at trial, and is entitled to treble damages plus a monetary civil penalty for each false record or statement.

COUNT 3 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE FALSE CLAIMS ACT:
CONSPIRING TO VIOLATE THE FALSE CLAIMS ACT (31 U.S.C. § 3729(a)(1)(C))

203. Relators reallege and incorporates by reference the prior paragraphs as though fully set forth herein.

204. Relators seek relief against Defendants under Section 3729(a)(1)(C) of the FCA, 31 U.S.C. § 3729(a)(1)(C).

205. As set forth above, Serono conspired with Brightstar, Maxim, Integrity, Proherant, physicians, and other health care professionals to offer or pay kickbacks in exchange for, or to induce them to purchase, order, or recommend the purchasing or ordering of the Covered Drugs in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), thereby causing false and fraudulent claims to be presented to federal health care programs seeking reimbursement for the Covered Drugs dispensed in connection with the kickback scheme.

206. Accordingly, Defendants conspired to commit violations of 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), in violation of 31 U.S.C. § 3729(a)(1)(C).

207. By reason of the Defendants conspiracy to violate 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), the United States has been damaged in a substantial amount to be determined

at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

COUNT 4 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE ARKANSAS MEDICAID FRAUD FALSE CLAIMS ACT,
ARK. CODE ANN. §§ 20-77-901 – 20-77-911

208. This is a claim for treble damages and civil penalties under the Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. §§ 20-77-901 – 20-77-911. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

209. Defendants violated the Arkansas Medicaid Fraud False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Arkansas as described herein.

210. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Arkansas.

211. The State of Arkansas, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Arkansas would not otherwise have paid.

212. By reason of these payments, the State of Arkansas has been damaged, and continues to be damaged, in a substantial amount.

COUNT 5 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE CALIFORNIA FALSE CLAIMS ACT,
CAL. GOV'T CODE §§ 12650 – 12656

213. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code §§ 12650 – 12656. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

214. Defendants violated the California False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented

to the State of California as described herein.

215. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of California.

216. The State of California, unaware of the false or fraudulent nature of these claims, paid such claims which the State of California would not otherwise have paid.

217. By reason of these payments, the State of California has been damaged, and continues to be damaged, in a substantial amount.

COUNT 6 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE COLORADO MEDICAID FALSE CLAIMS ACT,
COL. REV. STAT. ANN. §§ 25.5-4-303.5 – 25.5-4-310

218. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 – 25.5-4-310. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

219. Defendants violated the Colorado Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Colorado, as described herein.

220. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Colorado.

221. The State of Colorado, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Colorado would not otherwise have paid.

222. By reason of these payments, the State of Colorado has been damaged, and continues to be damaged, in a substantial amount.

COUNT 7 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE CONNECTICUT FALSE CLAIMS AND OTHER PROHIBITED ACTS UNDER STATE-ADMINISTERED HEALTH OR HUMAN SERVICES ACT ("CONNECTICUT FALSE CLAIMS ACT"), CONN. GEN. STAT. ANN. §§ 4-274 – 4-289

223. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. Ann. §§ 4-274 – 4-289. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

224. Defendants violated the Connecticut False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Connecticut, as described herein.

225. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Connecticut.

226. The State of Connecticut, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Connecticut would not otherwise have paid.

227. By reason of these payments, the State of Connecticut has been damaged, and continues to be damaged, in a substantial amount.

COUNT 8 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT, DEL. C. ANN. TIT. 6, §§ 1201 – 1211

228. This is a claim for treble damages and civil penalties under the Delaware False Claims and Reporting Act, Del. C. Ann. tit. 6, §§ 1201 – 1211. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

229. Defendants violated the Delaware False Claims and Reporting Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Delaware, as described herein.

230. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Delaware.

231. The State of Delaware, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Delaware would not otherwise have paid.

232. By reason of these payments, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount.

COUNT 9 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE DISTRICT OF COLUMBIA MEDICAID FRAUD ENFORCEMENT AND RECOVERY AMENDMENT ACT OF 2012, D.C. CODE ANN. §§ 2-381.01 – 2-381.10

233. This is a claim for treble damages and civil penalties under District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012, D.C. Code Ann. §§ 2-381.01 – 2-381.10. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

234. Defendants violated the District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012 by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the District of Columbia, as described herein.

235. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the District of Columbia.

236. The District of Columbia, unaware of the false or fraudulent nature of these claims, paid such claims which the District of Columbia would not otherwise have paid.

237. By reason of these payments, the District of Columbia has been damaged, and

continues to be damaged, in a substantial amount.

**COUNT 10 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE FLORIDA FALSE CLAIMS ACT,
FLA. STAT. ANN. §§ 68.081 – 68.092**

238. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 – 68.092. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

239. Defendants violated the Florida False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Florida as described herein.

240. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Florida.

241. The State of Florida, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Florida would not otherwise have paid.

242. By reason of these payments, the State of Florida has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 11 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE GEORGIA FALSE MEDICAID CLAIMS ACT,
GA. CODE ANN. §§ 49-4-168 – 49-4-168.6**

243. This is a claim for treble damages and civil penalties under Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 – 49-4-168.6. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

244. Defendant violated the Georgia False Medicaid Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Georgia, as described herein.

245. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Georgia.

246. The State of Georgia, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Georgia would not otherwise have paid.

247. By reason of these payments, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount.

COUNT 12 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE HAWAII FALSE CLAIMS TO THE STATE ACT, HAW. REV. STAT. §§ 661-21 – 661-31

248. This is a claim for treble damages and civil penalties under the Hawaii False Claims to the State Act, Haw. Rev. Stat. §§ 661-21 – 661-31. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

249. Defendants violated the Hawaii False Claims to the State Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Hawaii, as described herein.

250. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Hawaii.

251. The State of Hawaii, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Hawaii would not otherwise have paid.

252. By reason of these payments, the State of Hawaii has been damaged, and continues to be damaged, in a substantial amount.

COUNT 13 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE ILLINOIS FALSE CLAIMS ACT, 740 ILL. COMP. STAT. ANN. §§ 175/1 – 175/8

253. This is a claim for treble damages and civil penalties under the Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. §§ 175/1 – 175/8. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

254. Defendants violated the Illinois False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Illinois, as described herein.

255. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois.

256. The State of Illinois, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Illinois would not otherwise have paid.

257. By reason of these payments, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount.

COUNT 14 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT, IND. CODE ANN. §§ 5-11-5.5-1 – 5-11-5.5-18

258. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblowers Protection Act, Ind. Code Ann. §§ 5-11-5.5-1 – 5-11-5.5-18. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

259. Defendants violated the Indiana False Claims and Whistleblowers Protection Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing

false claims to be presented to the State of Indiana, as described herein.

260. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Indiana.

261. The State of Indiana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Indiana would not otherwise have paid.

262. By reason of these payments, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount.

COUNT 15 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE IOWA FALSE CLAIMS ACT, IOWA CODE ANN. §§ 685.1 – 685.7

263. This is a claim for treble damages and civil penalties under the Iowa False Claims Act, Iowa Code Ann. §§ 685.1 – 685.7. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

264. Defendants violated the Iowa False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Iowa, as described herein.

265. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Iowa.

266. The State of Iowa, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Iowa would not otherwise have paid.

267. By reason of these payments, the State of Iowa has been damaged, and continues to be damaged, in a substantial amount.

COUNT 16 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW, LA. STAT. ANN. §§ 437.1 – 440.16

268. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Stat. Ann. §§ 437.1 – 440.16. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

269. Defendants violated the Louisiana Medical Assistance Programs Integrity Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Louisiana, as described herein.

270. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Louisiana.

271. The State of Louisiana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Louisiana would not otherwise have paid.

272. By reason of these payments, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount.

COUNT 17 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE MARYLAND FALSE HEALTH CLAIMS ACT, MD. CODE ANN., HEALTH-GEN. §§ 8-101 – 8-111

273. This is a claim for treble damages and civil penalties under the Maryland False Health Claims Act, Md. Code Ann., Health-General §§ 8-101 – 8-111. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

274. Defendants violated the Maryland False Health Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Maryland, as described herein.

275. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Maryland.

276. The State of Maryland, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Maryland would not otherwise have paid.

277. By reason of these payments, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount.

COUNT 18 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE MASSACHUSETTS FALSE CLAIMS LAW, MASS. GEN. LAWS ANN. CH. 12, §§ 5A – 5O

278. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Law, Mass. Gen. Laws Ann. ch. 12, §§ 5A – 5O. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

279. Defendants violated the Massachusetts False Claims Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the Commonwealth of Massachusetts, as described herein.

280. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth of Massachusetts.

281. The Commonwealth of Massachusetts, unaware of the false or fraudulent nature of these claims, paid such claims which the Commonwealth of Massachusetts would not otherwise have paid.

282. By reason of these payments, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 19 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE MICHIGAN MEDICAID FALSE CLAIM ACT,
MICH. COMP. LAWS ANN. §§ 400.601 – 400.615**

283. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claim Act, Mich. Comp. Laws Ann. §§ 400.601 – 400.615. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

284. Defendants violated the Michigan Medicaid False Claim Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Michigan, as described herein.

285. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Michigan.

286. The State of Michigan, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Michigan would not otherwise have paid.

287. By reason of these payments, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 20 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE MINNESOTA FALSE CLAIMS ACT,
MINN. STAT. ANN. §§ 15C.01 – 15C.16**

288. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act, Minn. Stat. Ann. §§ 15C.01 – 15C.16. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

289. Defendants violated the Minnesota False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Minnesota, as described herein.

290. As a result of the misconduct alleged herein, Defendants knowingly made, used,

or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Minnesota.

291. The State of Minnesota, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Minnesota would not otherwise have paid.

292. By reason of these payments, the State of Minnesota has been damaged, and continues to be damaged, in a substantial amount.

COUNT 21 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE MONTANA FALSE CLAIMS ACT, MONT. CODE ANN. §§ 17-8-401 – 17-8-416

293. This is a claim for treble damages and civil penalties under Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 – 17-8-416. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

294. Defendants violated the Montana False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Montana, as described herein.

295. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Montana.

296. The State of Montana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Montana would not otherwise have paid.

297. By reason of these payments, the State of Montana has been damaged, and continues to be damaged, in a substantial amount.

COUNT 22 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE NEVADA SUBMISSION OF FALSE CLAIMS TO STATE OR LOCAL GOVERNMENT ACT, NEV. REV. STAT. ANN. §§ 357.010 – 357.250

298. This is a claim for treble damages and civil penalties under the Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010 – 357.250. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

299. Defendants violated the Nevada Submission of False Claims to State or Local Government Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Nevada, as described herein.

300. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Nevada.

301. The State of Nevada, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Nevada would not otherwise have paid.

302. By reason of these payments, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount.

COUNT 23 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE NEW HAMPSHIRE MEDICAID FRAUD AND FALSE CLAIMS LAW, N.H. REV. STAT. ANN. §§ 167:61-B – 167:61-E

303. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims Law, N.H. Rev. Stat. Ann. §§ 167:61-b – 167:61-e. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

304. Defendants violated the New Hampshire Medicaid Fraud and False Claims Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing

false claims to be presented to the State of New Hampshire, as described herein.

305. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Hampshire.

306. The State of New Hampshire, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Hampshire would not otherwise have paid.

307. By reason of these payments, the State of New Hampshire has been damaged, and continues to be damaged, in a substantial amount.

COUNT 24 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE NEW JERSEY FALSE CLAIMS ACT,
N.J. STAT. ANN. §§ 2A:32C-1 – 2A:32C-18

308. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 – 2A:32C-18. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

309. Defendants violated the New Jersey False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Jersey, as described herein.

310. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Jersey.

311. The State of New Jersey, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Jersey would not otherwise have paid.

312. By reason of these payments, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount.

COUNT 25 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE NEW MEXICO FRAUD AGAINST TAXPAYERS ACT,
N.M. STAT. ANN. §§ 44-9-1 – 44-9-14,
AND THE NEW MEXICO MEDICAID FALSE CLAIMS ACT,
N.M. STAT. ANN. §§ 27-14-1 – 27-14-15

313. This is a claim for treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 – 44-9-14, and the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 – 27-14-15. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

314. Defendants violated the New Mexico Fraud Against Taxpayers Act and the New Mexico Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Mexico, as described herein.

315. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Mexico.

316. The State of New Mexico, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Mexico would not otherwise have paid.

317. By reason of these payments, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount.

COUNT 26 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE NEW YORK FALSE CLAIMS ACT,
N.Y. FIN. LAW §§ 187 – 194

318. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. Fin. Law §§ 187 – 194. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

319. Defendants violated the New York False Claims Act by engaging in the

fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New York, as described herein.

320. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New York.

321. The State of New York, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New York would not otherwise have paid.

322. By reason of these payments, the State of New York has been damaged, and continues to be damaged, in a substantial amount.

COUNT 27 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE NORTH CAROLINA FALSE CLAIMS ACT,
N.C. GEN. STAT. ANN. §§ 1-605 – 1-618

323. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. Ann. §§ 1-605 – 1-618. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

324. Defendants violated the North Carolina False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of North Carolina, as described herein.

325. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of North Carolina.

326. The State of North Carolina, unaware of the false or fraudulent nature of these claims, paid such claims which the State of North Carolina would not otherwise have paid.

327. By reason of these payments, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 28 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT,
OKL. STAT. ANN. TIT. 63, §§ 5053 – 5054**

328. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okl. Stat. tit. 63, §§ 5053 – 5054. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

329. Defendants violated the Oklahoma Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Oklahoma, as described herein.

330. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Oklahoma.

331. The State of Oklahoma, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Oklahoma would not otherwise have paid.

332. By reason of these payments, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 29 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE RHODE ISLAND STATE FALSE CLAIMS ACT,
R.I. GEN. LAWS ANN. §§ 9-1.1-1 – 9-1.1-9**

333. This is a claim for treble damages and civil penalties under the Rhode Island State False Claims Act, R.I. Gen. Laws Ann. §§ 9-1.1-1 – 9-1.1-9. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

334. Defendants violated the Rhode Island State False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Rhode Island, as described herein.

335. As a result of the misconduct alleged herein, Defendants knowingly made, used,

or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Rhode Island.

336. The State of Rhode Island, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Rhode Island would not otherwise have paid.

337. By reason of these payments, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount.

COUNT 30 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE TENNESSEE FALSE CLAIMS ACT, TENN. CODE ANN. §§ 4-18-101 – 4-18-108 AND THE TENNESSEE MEDICAID FALSE CLAIMS ACT, TENN. CODE. ANN. §§ 71-5-181 – 71-5-185

338. This is a claim for treble damages and civil penalties under the Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 – 4-18-108, and the Tennessee Medicaid False Claims Act, Tenn. Code. Ann. §§ 71-5-181 – 71-5-185. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

339. Defendants violated the Tennessee False Claims Act and the Tennessee Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Tennessee, as described herein.

340. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Tennessee.

341. The State of Tennessee, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Tennessee would not otherwise have paid.

342. By reason of these payments, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 31 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION LAW,
TEX. HUM. RES. CODE ANN. §§ 36.001 – 36.132**

343. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

344. Defendants violated the Texas Medicaid Fraud Prevention Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Texas, as described herein.

345. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Texas.

346. The State of Texas, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Texas would not otherwise have paid.

347. By reason of these payments, the State of Texas has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 32 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE VERMONT FALSE CLAIMS ACT,
VT. STAT. ANN. TIT. 32, §§ 630 – 642**

348. This is a claim for treble damages and civil penalties under the Vermont False Claims Act, Vt. Stat. Ann. tit. 32, §§ 630 – 642. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

349. Defendants violated the Vermont False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State as Vermont, as described herein.

350. As a result of the misconduct alleged herein, Defendants knowingly made, used,

or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Vermont.

351. The State of Vermont, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Vermont would not otherwise have paid.

352. By reason of these payments, the State of Vermont has been damaged, and continues to be damaged, in a substantial amount.

COUNT 33 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT, VA. CODE ANN. §§ 8.01-216.1 – 8.01-216.19

353. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 – 8.01-216.19. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

354. Defendants violated the Virginia Fraud Against Taxpayers Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the Commonwealth of Virginia, as described herein.

355. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Commonwealth of Virginia.

356. The Commonwealth of Virginia, unaware of the false or fraudulent nature of these claims, paid such claims which the Commonwealth of Virginia would not otherwise have paid.

357. By reason of these payments, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount.

COUNT 34 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE WASHINGTON MEDICAID FRAUD FALSE CLAIMS ACT, WASH. REV. CODE ANN. §§ 74.66.005 – 74.66.130

358. This is a claim for treble damages and civil penalties under the Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. §§ 74.66.005 – 74.66.130. Relators reallege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

359. Defendants violated the Washington Medicaid Fraud False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Washington, as described herein.

360. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Washington.

361. The State of Washington, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Washington would not otherwise have paid.

362. By reason of these payments, the State of Washington has been damaged, and continues to be damaged, in a substantial amount.

PRAYER FOR RELIEF

WHEREFORE, Relator requests that judgment be entered against Defendants as follows:

(a) treble the Government's damages in an amount determined at trial, plus the maximum statutorily-allowed penalty for each false claim submitted in violation of the FCA or State statute set forth above;

(b) the applicable administrative civil penalties of for each violation of the AKS and State-equivalent statute, as well as an assessment of not more than three times the amount of

remuneration offered, paid, solicited or received, without regard to whether a portion of that amount was offered, paid or received for a lawful purpose;

(c) an award of costs and the maximum Relator award allowed pursuant to the FCA and State statute set forth above; and

(d) such further relief as is proper.

Dated: April 19, 2018

Respectfully submitted,

/s/ W. Mark Lanier

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